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Creating a Collapsible Sling Lift Capable of Transporting Patients Between Various Locations

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Creating a Collapsible Sling Lift Capable of Transporting Patients Between Various Locations

By

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A thesis submitted to the faculty of the University of Mississippi in partial fulfillment of the requirements of the Biomedical Engineering Department and the Sally McDonnell Barksdale Honors College.

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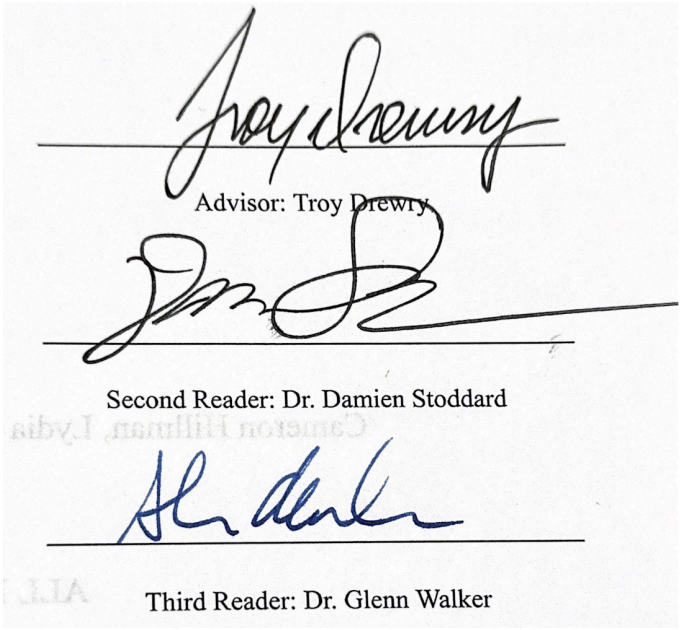
Approved by:



Advisor: Troy Drewry

Second Reader: Dr. Damien Stoddard

Third Reader: Dr. Glenn Walker

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Additionally, we would like to thank our 4th group member, Matthew Mosset, for his commitment and aid in this project. Along with this, we would like to thank Jacob Schwartz for his aid in formulating our CAD design and helping our vision turn into a tangible product.

Dedication

We would like to dedicate this project to our families, who continually display profuse love and support for us through all that we do.

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Abstract

As Senior Biomedical Engineering students at the University of Mississippi, we, Lainey Hillman, Lydia Miller, and Macey Ross, are required to complete a final senior capstone for our department. This project aims to provide a solution to a current unmet clinical need in the healthcare industry, thus our team sought to improve the lack of transportability of sling lifts. The current sling lifts on the market display numerous issues: heavy, bulky, use confined to certain areas, and use specific for only one type of transportation. To combat these problems, we designed a sling lift that was lightweight, collapsible, safe, and easy to use/transport as detailed in the following thesis report. Future work planned for this product will include producing a to-scale prototype, subjecting the prototype to testing/trials, patenting our device, and seeking FDA approval for the purpose of using this device in clinical settings.

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Introduction

A sling lift is a medical device that is used to transport patients from one location to another (Anderson). These patients are typically unable to walk on their own, thus requiring aid in moving from bed to wheelchair, wheelchair to car, wheelchair to chair, etc.. These patients are most often elderly and are cared for by their elderly spouses, and because of this, it is often difficult for these caregivers to operate and transport heavy sling lifts, and the use of these lifts is typically limited to one room, area, or home (iHealthcareAnalyst, Inc.). Along with this, sling lifts are traditionally expensive and have the potential to cause harm to patients or caregivers due to pinching of skin or support failure (Anderson). Furthermore, some patients require the purchase of multiple sling lifts that serve unique purposes. For example, a patient who uses a ceiling sling lift that provides transport from bed to wheelchair would need a different sling lift to provide transport from wheelchair to car. Thus, the total cost of multiple sling lifts is much greater than that of a single lift that can perform all the necessary functions.

We designed a sling lift that eliminates each of these problems. The lift is collapsible and capable of being carried between locations in addition to being lightweight. Since the sling lift is not excessively heavy, this maximizes the ease in which caregivers can perform their necessary tasks which include moving the sling lift itself. Along with this, our design minimizes risk occurrence and the probability of failure. This sling lift provides aid in numerous situations, thus replacing the need for multiple sling lifts for a single person, helping to make the total price substantially less than current costs that patients are expected to pay for multiple sling lifts that each perform a unique function. Overall, we believe our design is an improvement to the current sling lifts on the market as it focuses on the satisfaction of the patients and caregivers.

Literature Review

What is a Sling Lift?

A sling lift is categorized as a medical device that is used to transport patients that are immobile or otherwise unable to move without assistance. The main purpose of the original sling lift invention was to preserve the patients' independence and integrity while providing them with care that meets their specific needs (Anderson). The sling lift originated in the automobile manufacturing industry and was traditionally used as a method for lifting and lowering heavy car machinery such as car engines, as depicted in *part A* of **Figure 1** (Next Health). Eventually, this same concept was applied to the healthcare industry, allowing the lifting and lowering of patients using the same technology, as depicted in *part B* of **Figure 1**.

Figure 1*: This image serves as a reference for a sling lift. Depicted in part A of this image is the engine lift from which the idea of the sling lift was derived (Tuffcare Store). Depicted in part B of this image is a conventional floor based sling lift that is used in extended care facilities, hospitals, and in residential settings (Worcest Store). The citations for these images can be found in the Bibliography section of this paper.*

There are many different types of sling lifts available on the market today that each provide a different function. Certain lifts are used to help patients move from the sitting position to the standing position, while others are able to fully move a patient from their bed to a chair (Marquis). In hospital and caregiving settings, the most frequently used type of lift is a powered floor based dependent lift that helps caregivers move patients between a bed and a chair or move from a chair to another chair (Kucera, et. al.).

Based on data from 2023, the global medical lifting sling market was estimated at over a billion dollars, and is projected to grow at a compound annual growth rate of 7.6% between 2024 and 2030. This growth projection is due to a number of factors, with one of the most prevalent being the aging of the worldwide population, as depicted in **Figure 2** (Knickman and Snell). Other factors include an overall positive trend in the prevalence of chronic disorders that require long term assisted care and the rise in the number of individuals that are limited by physical disabilities (Knickman and Snell). Additionally, there is a strong correlation between the need for these kinds of lifts and the rise in the number of elderly individuals due to the high occurrence of injuries within the aging population, with the CDC reporting in 2023 that there are roughly 300,000 elderly people hospitalized due to hip fractures on an annual basis (CDC).

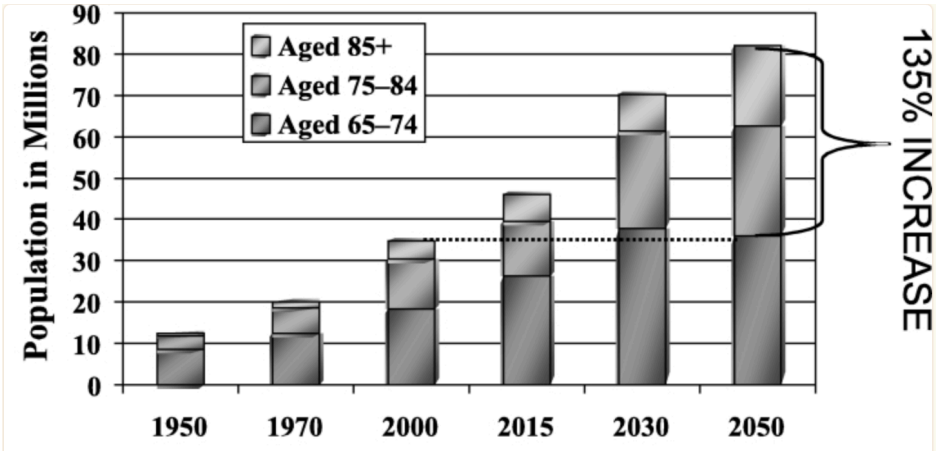


Figure 2*: The image above was derived from a National Institute of Health (NIH) publication that was created in conjunction with Health Services Research (HSR). Based on the American population projection alone, it is predicted that by 2050 there will be a 135% increase in the 75 to 85+ age demographic (Knickman and Snell).*

One of the major limitations when it comes to making sling lifts accessible for the general patient population is price. Depending on the needs of the patient and the type of lift, a given device may cost upwards of twenty thousand US dollars (Crail). The more complex the device is and the more weight the lift is required to support strongly correlates to the device being more expensive for the patient, with complex overhead lifts costing the most. Many of these lifts are also created with one time installation in mind, helping the patient move from their bed to a wheelchair or from their wheelchair to their bed, preventing these devices from being used anywhere but at the patient's home or care facility (Crail). Another major limitation of sling lifts concerns to the safety of both the patient and the operator. Per healthcare guidelines, healthcare providers should not lift anything heavier than thirty pounds (Kucera, et. al.). With this in mind, stronger lifting mechanisms also come with a larger price tag, tying back to the first listed limitation of sling lifts (Crail).

Due to the limited solutions on the market, there is a large gap between patient and caregiver needs and current sling lift devices. MLLM Innovations designed the ATLAS to help combat the shortcomings of the array of devices available for purchase. The name "ATLAS" stands for "A Transportable Lightweight Automated Sling lift". As the name suggests, this device was designed to provide everything that a patient, customer, and caregiver could need. Not only is the device functional and safe, but it is also transportable, meaning that patients will no longer be limited to only using this device in their home. Caregivers can safely and easily collapse and transport the lift so that it can be used for traveling purposes. This vastly expands the opportunity for individuals who have difficulty moving on their own to be able to travel and attend events that they may have otherwise missed.

Prior Art Search

A crucial part of our product design process was analyzing products previously made and readily available on the market to ensure our design ideas are novel and do not impede on pre-existing models of sling lifts. We identified and drew inspiration from six separate sling lift device designs.

Reference 1: *Patient Lift System* US10555856B2

Reference 1 is a patent for a sling lift that includes the lift itself, a carry bar, and a hand control. This lift system was made to be mounted on the ceiling and utilize a track and trolley system to lift and carry patients over a short distance. The size of the patient lift system is very large, especially for small rooms or rooms with low ceilings, and does not have the ability to be easily removed and repurposed for traveling purposes.

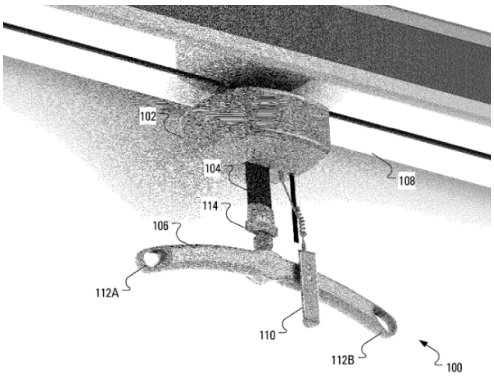


Figure 3: Prior Art Reference #1

Reference 2: *Hydraulic Jack and Patient Lifting Device* EP0000443B1

Reference 2 is a patent for a mobile sling lift that is operated using a hydraulic jack. In order to operate the device, there is a release valve which can be used to control the pressure being utilized to lift and lower patients. To lower the patients, the operator either has to release

the pump handle or use a separate hand to press a button. Either of these options are undesirable, as convenience is limited.

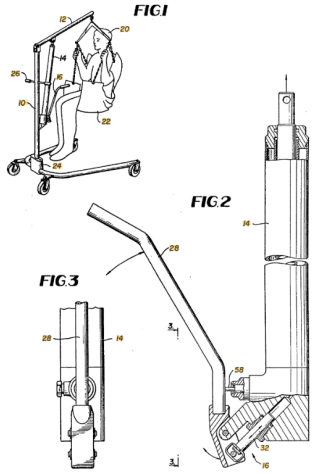


Figure 4: Prior Art Reference #2

Reference 3: *Lift System with Lowering Mechanism* US10610431B2

Reference 3 is a patent for a rail-mounted overhead patient sling lift system. The lift is controlled by an electric system that can receive, transmit, store, display, and process data that is input from various sources. This device is also able to rotate in either a clockwise or counterclockwise manner, and has the ability to both lift and lower patients. Once again, one of the major drawbacks with this specific sling lift is that it is mounted to the wall and thus does not offer a solution for patients needing a lift while traveling.

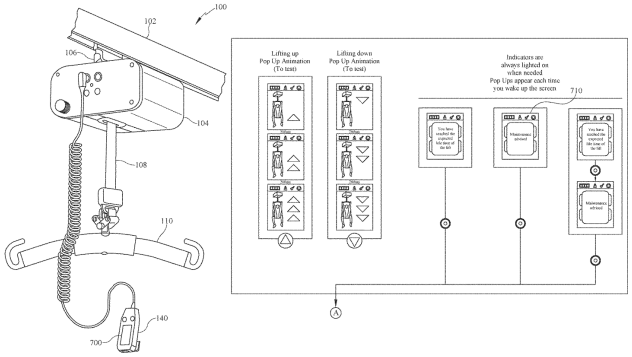


Figure 5: Prior Art Reference #3

Reference 4: *Portable Transfer Chair and Lift* US011154446B2

Reference 4 is a patent for a portable transfer chair and lift as well as a special webbing configured to support patients that require lifting assistance. This patent for the transferable chair includes additional handles that can be used to help transfer a patient manually. This mesh webbing is water resistant and was designed for patients that need assistance with using the restroom and with showering as well as bathing.

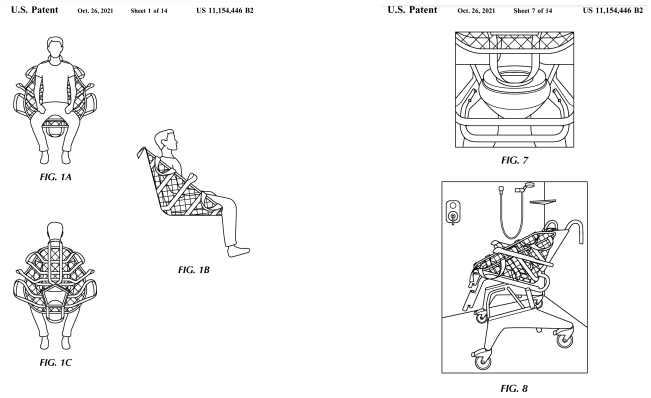


Figure 6: Prior Art Reference #4

Reference 5: *Patient Support Lift Assembly* US20160302985A1

Reference 5 is a patent that describes a device that has multiple frames that can be used to help raise and lower a patient to a height in which a caregiver may access the patient comfortably. The device includes wheels so that it can be used to mobilize the patient if needed by the caregiver. This device also has the ability to fold on itself to become portable and transportable.

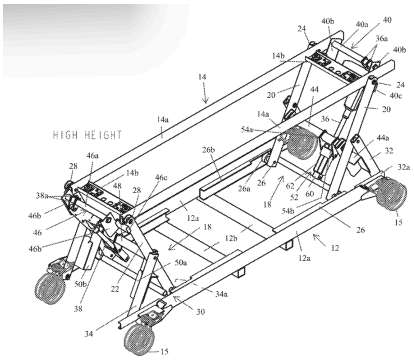


Figure 7: Prior Art Reference #5

Reference 6: ***Sling Bar or Lift Strap Connector having an Integrated Scale with Tilt Compensation*** **EP2862552B1**

Reference 6 is a patent which describes an invention that is meant to be used as a type of scale for patients with overhead lifts. Since patients in need of a lift often are unable to walk and stand on a scale, this device was made as a way for patients to be weighed by their caregivers.

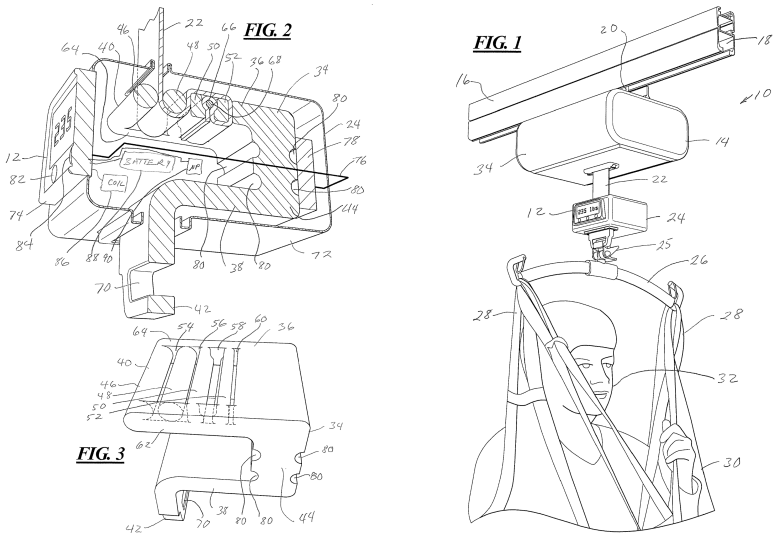


Figure 8: Prior Art Reference #6

Problem Statement

A design for an affordable, portable, lightweight, automated, and easy to use lift that effectively raises and lowers immobilized patients while prioritizing the safety of patients and caregivers.

Value Proposition

Our team aims to increase patient and caregiver satisfaction by creating a sling lift that is collapsible, light, cost effective, multi-purposeful, safe, and easy to use. We estimate that patients typically purchase two different sling lifts for roughly $2,000 each on average, with some sling lifts on the market reaching prices of up to $20,000 (MDS). It is important to note that there are a wide range of prices for a wide variety of types of sling lifts, yet the lifts that are on-par with the quality of our lift are around $2,000. We plan to sell our product for roughly $2,000 as well, thus our customers will be saving $2,000 by purchasing our singular lift instead of two separate lifts. It is also important to note that many patients have more than two lifts, in which case the total savings would increase.

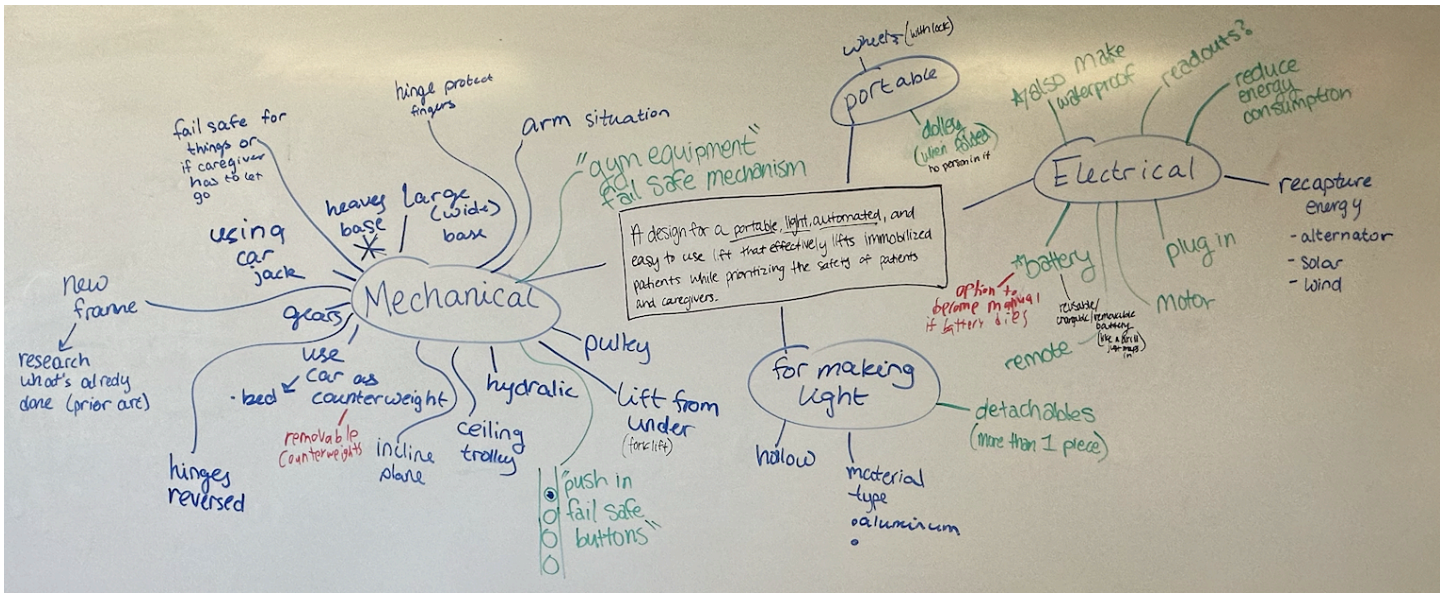
Brainstorming Process and Notes

Early Brainstorming

In the beginning of our project, we spent a significant amount of time brainstorming for the purpose of finding solutions for the problem at hand. We began by considering our problem statement, and we broke down the components of the statement to be individually addressed through our brainstorming process. These subsets included the mechanical system, the electrical system, the weight of the product, and the portability of the product. The resulting brainstorming diagram is displayed below in **Figure 1**.

Potential ideas concerning the mechanical aspects of the product included utilizing a heavy and wide base, a fail-safe system to ensure injury is avoided for both the patient and caregiver, a hydraulic system, a pulley system, and counterweights. The goal was to try to come up with the most stable and effective lifting mechanism to ensure the safety of both the care provider and the patient being lifted. Pertaining to the electrical aspects of the product, some ideas included using reusable battery packs, utilizing a system to recapture energy, making the product waterproof, using a remote to control the lifting mechanism, and more. The main focus was to ensure that the device could be used under any circumstances and would be as efficient as possible. To make the product lightweight, the potential ideas included making the product have multiple detachable pieces for easy transport, using a lightweight material, such as high-strength aluminum 6061, and making the majority of the product hollow. Finally, to ensure the product is transportable, the potential ideas included adding wheels with locks and including multiple detachable and collapsible pieces that can be easily transported. Both the lightweight and transportable concepts were carefully discussed to avoid compromising the integrity of the lift.

Figure 9: Brainstorming Diagram

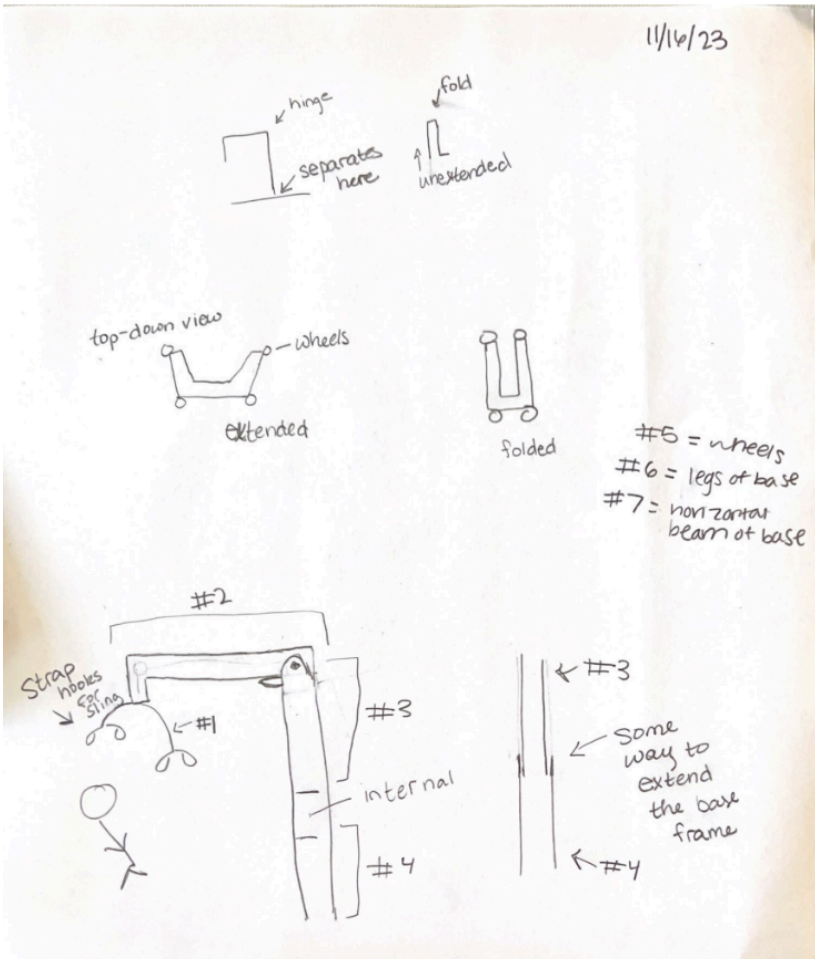


Previous Designs

After completing the brainstorming diagram, the team combined their most favorable ideas into a rough design. This rough sketch of the initial design is displayed below in **Figure 2**. This initial design included 7 specific parts. Part 1 was the hooks to which the straps of the sling would attach. Part 2 was the top, horizontal bar which would be attached to the top, vertical bar (Part 3) by a backwards hinge. This backwards hinge would allow for compact folding and act as a fail-safe: failure of the hinge would be less likely to result in the patient falling to the ground. Part 3 would be capable of sliding within Part 4 (lower, vertical bar) for the purpose of lifting and lowering the patient. Part 5 included the lockable wheels attached to the base of the lift, allowing for easy and safe transport. Part 6 included the extendable legs of the base that would be capable of folding inward to make the base more compact, and Part 7 was the horizontal beam of the base. To collapse the product for transport, Part 3 would contract within Part 4, Part 2 would swing 270 degrees clockwise (based on the direction the product is facing in the sketch), Part 6 would fold inward, and the base would detach from the Part 4. The material used for this

product would mainly consist of hollow, high-strength aluminum 6061 bars, allowing for the product to be light, and the initial mechanical and electrical system decided upon was a pulley system with rechargeable battery packs.

Figure 10: Rough Sketch of the Initial Design



Final Design

After transferring the initial design into a CAD drawing. It was found that the backwards hinge would not provide the fail-safe that the team hoped. Thus, this design aspect was replaced with a pin and socket, and the stress tests proved that this was sufficient to support a patient of 350 lbs with a factor of safety of 2 and provide the fail-safe for which the team was searching. Along with this, the team discovered a more effective lifting and lowering mechanism.

Therefore, the pulley system was replaced with a motor-driven power screw system. For this new system, what was initially Part 4 of the product would include a long, internal power screw attached to a worm gear and worm that would be controlled by a motor and battery packs. To raise the lift, the battery packs will engage the motor, causing the screws to rotate and move the top section upwards. To lower the lift, the motor would reverse directions, and the screws would rotate in the opposite direction. These changes are displayed in the final CAD drawing below, in **Figures 11-12**, along with the associated stress test results, in **Figures 13-14**.

Figure 11: Final CAD Drawing: Frame

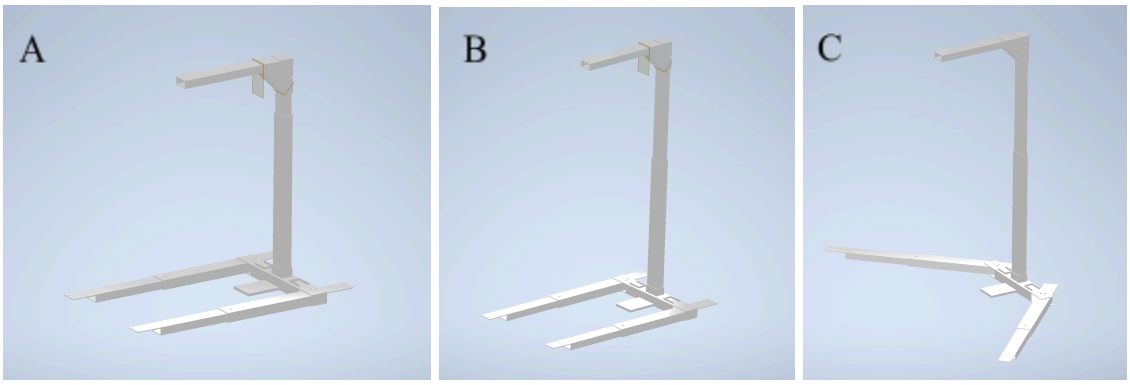


Figure 11*: Inventor Drawings by Lydia Miller and Jacob Schwartz. The device frame is 53.3 inches tall when fully lowered and 74.3 inches tall when fully extended. The base dimensions are 56.50 inches by 30 inches when the legs are square and 95.7 inches wide when legs are splayed. Note: this drawing does not include externally purchased components, which are bolts, pins, the motor, battery packs, patient sling, and wheels. Also, the dimensions listed do not include the wheels. (11a) Device legs are square, and the device is fully lowered. (11b) Device legs are square, and the device is fully raised. (11c) Device legs are splayed, and the device is at an intermittent height.*

Figure 12: Final CAD Drawing: Power Screw System

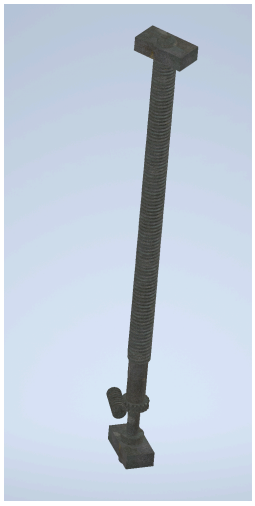


Figure 12*: Inventor Drawings by Lydia Miller and Jacob Schwartz. The power screw system has a total height of 31.37 inches. The power screw system fits inside of the lower of the two vertical bars. The upper of the two vertical bars sits on top of the top bar of the power screw system. The bottom bar of the power screw system will be welded on the inside of the lower vertical bar and sit flush to the bottom of that bar. The worm of the worm and worm gear pair will be attached to the motor shaft. Note: There will be a nut welded to the top and bottom of the power screw in order to prevent the removal of the platform that sits on it.*

Figure 13: Full Assembly Stress Test Results

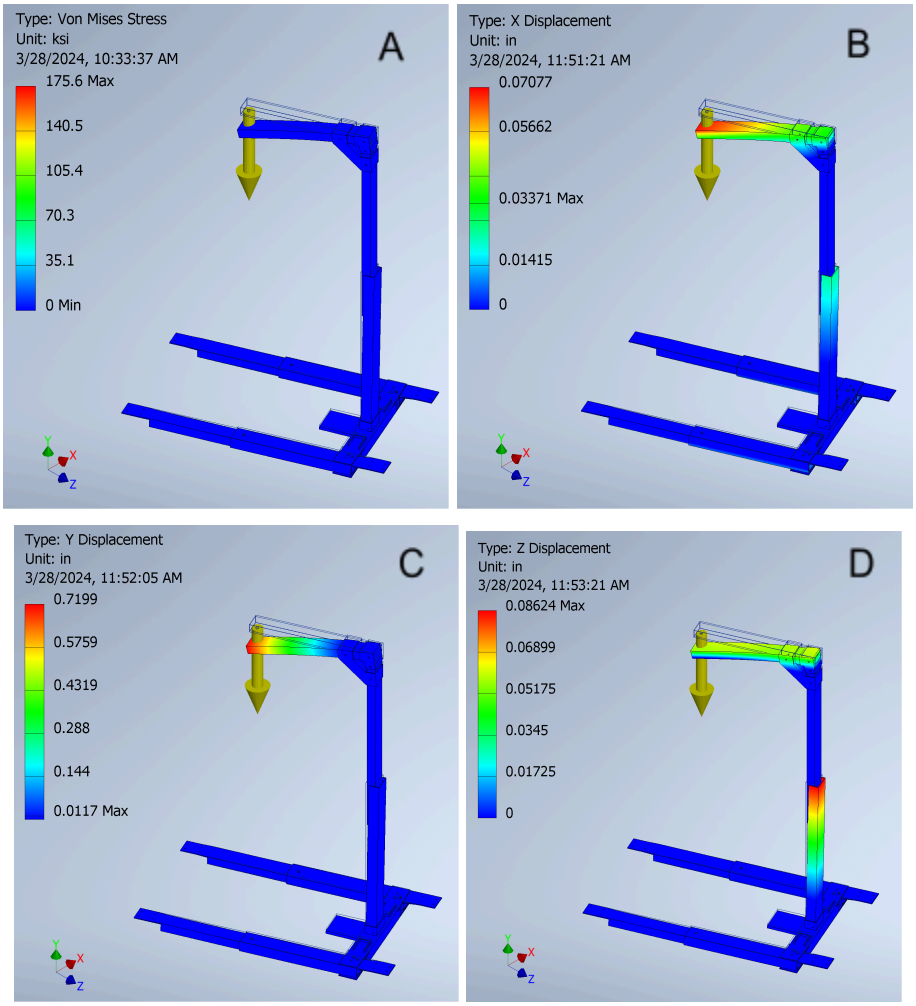


Figure 13*: Inventor Drawings by Lydia Miller and Jacob Schwartz. The model shows the frame with the power screw system inside. The 700-pound load was applied at the location indicated by the arrow.*

Figure 14: Power Screw System Stress Test Results

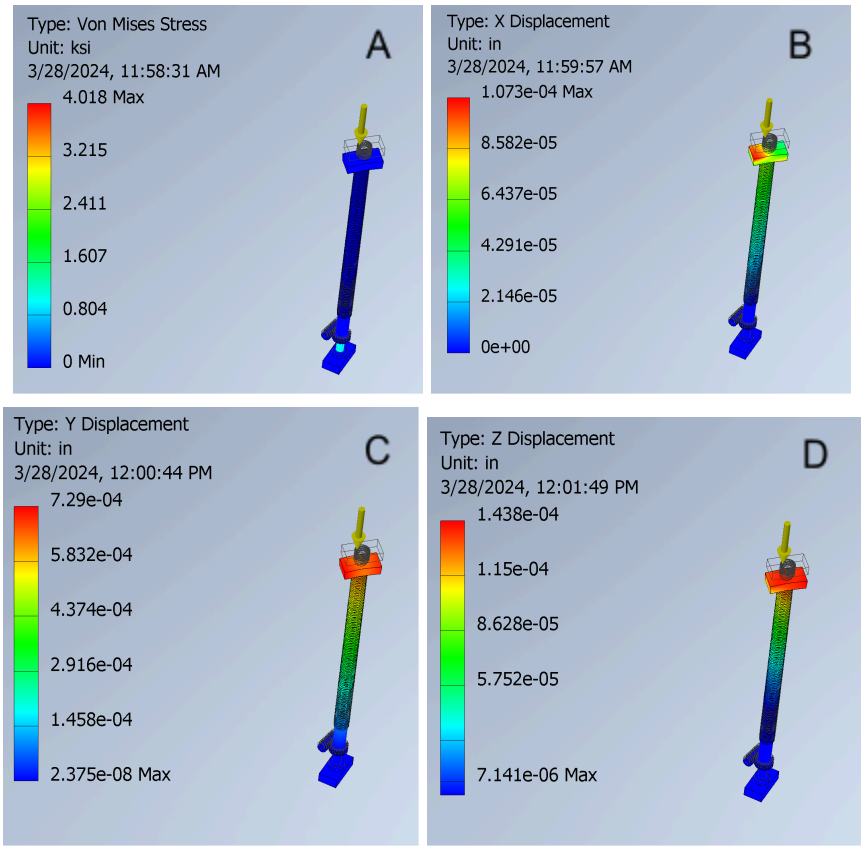


Figure 14*: Inventor Drawings by Lydia Miller and Jacob Schwartz. The model shows only the power screw system that is inside the frame. A 715-pound load was applied at the location indicated by the arrow instead of the 700-pound load in order to generously account for the weight of the section of frame that sits upon it.*

The benefits of our final design include the following:

1. **Prevention of Failure/User Injury**

    a. Pin and Socket

    As previously described, the backwards hinge did not provide the desired level of safety, failing to provide a successful trial run, yet the pin and socket system does act as an adequate fail-safe system. The top, horizontal bar is essentially locked in place which prevents failure of the supporting bar. Furthermore, because a hinge is not utilized, the potential of caregivers fingers' being pinched while collapsing the product is

eliminated. Along with this, the bottom, vertical bar is locked into the base by another pin and socket.

b. Power Screw

The previous design utilized a pulley system. This pulley system would not only make the device difficult to collapse, but it would also be difficult to house inside of the structure. By replacing this system with the power screw system, this problem is eliminated.

c. The product is lightweight.

Because the product is mainly composed of hollow, high-strength aluminum 6061, it can be easily manipulated and transported by caregivers. Through the team's market research, it was determined that many caregivers of elderly patients are elderly themselves, limiting their ability to lift heavy machinery. By ensuring that the product is lightweight, this issue is eliminated.

d. The hooks prevent the straps from slipping out unintentionally.

Each hook included is nearly closed in a complete loop. This feature prevents the straps of the sling from unintentionally being removed from the hooks.

2. Replaces the need for multiple sling lifts.

a. The lift is collapsible.

Because the product is capable of being disassembled/reassembled in only a few minutes, it can be brought with patients to numerous locations. The situations in which the product can be used include transporting the patient

from bed to wheelchair, wheelchair to car, wheelchair to clinic seating, and more. Through the team's market research, it was determined that the many users of sling lifts own multiple lifts for different particular situations. For example, a patient may have a ceiling lift within one area of their home and a separate lift for transferring into a car.

b. The lift is light.

   Because the product is lightweight, its disassembled pieces can easily be picked up and placed in the car for transportation. Furthermore, many electric wheelchairs have storage compartments capable of housing the parts of the product for transport into different locations.

3. Easy to use.

a. Electrical system powered by four battery packs.

   The system in use is similar to that of a drill with detachable battery packs. These battery packs will seamlessly slide into place on the back of the vertical bar and provide power to the power screw system for lowering or lifting the patient.

b. Lifting/Lowering controlled by a button.

   Upon the external of the lift itself, a button will be included, and by a simple press of this button, the screw will rotate into the rod or out of the rod. The controlling system for this action is similar to that of a battery pack driven drill that includes a switch to change the direction of rotation.

Materials

The team decided upon using high-strength aluminum 6061 to create the majority of the structure due to the fact that it is lightweight, resistant to damage, and supportive. Furthermore, the aluminum bars utilized are hollow, adding to the product's capability of being lightweight and transportable. The internal lifting mechanism is steel to ensure the highest durability of the cost and size required. The lead screw is a 24 inch long, 1 ½ in - 4 ACME Class 2G lead screw from McMaster-Carr. The four battery packs are from the Dewalt brand. They come in a two-pack with a charger included, as these batteries are rechargeable. The batteries are capable of outputting 60 Volts and have a weight of 4.51 lbs each. The motor is a 115 V, 1,725 RPM, ⅓ horsepower motor from Grainger. The sling lift is made to be compatible with any sling that has four straps to hook onto a lift. The pins and snap buttons are made of steel to ensure maximum durability. The legs also have a total of 4 swivel with braking wheel casters for moveability while in use. These wheels are from Uline. Furthermore, the product includes a bag that can be used for carrying the individual parts when they are collapsed. This bag will be made of durable polyester.

Design Overview

Our design features a high-strength aluminum 6061 frame with a steel power screw lifting mechanism and images of the components are depicted with proper dimensions in **Figures 15-28**. The device parts are easy to separate and collapse to ensure a portable design. The power screw system will be contained inside of the lower, vertical bar (**Fig 18**), excluding the worm, which will be attached to the provided motor. We will provide a 115 volt motor with ⅓ horsepower and 1,725 rpm, along with four 60 volt batteries, to power the power screw system.

The user will be able to turn the motor on and off, as well as change the direction of rotation, all by pressing a few buttons.

When the motor is turned on, it will rotate the worm and worm gear (torsion ratio 1:20) (**Fig 25**). This worm gear will be welded to a 3 inch rod that is, in turn, welded to the power screw (**Fig 27**). The worm gear will cause the power screw to rotate, which will move the platform (**Fig 28**) upwards or downwards depending on the direction of rotation.

The user will be able to put together the parts of the device by using dowel pins with dimensions of 5/16 inches in diameter and 4.72 inches in length. Dowel pins of these specifications will be used to lock the leg pieces (**Fig 16**) to the base piece (**Fig 15**). On each side of the base (**Fig 15**), there will be a separate double-sided button pin to lock the leg extensions (**Fig 17**) in place, and another separate single-sided button pin to secure the main leg pieces (**Fig 16**) to the base at the proper angle. Then, the user will insert the lower vertical bar (**Fig 18**) into the slot on the base and lock it into place using a dowel pin with the specifications previously mentioned. The upper vertical bar (**Fig 19**) will slide into the lower vertical bar (**Fig 18**) and sit on top of the power screw mechanism housed inside the lower vertical bar (**Fig 18**). The bracer bar piece (**Fig 20**) will then be slid onto the upper vertical bar (**Fig 19**) and secured into the lower hole using a dowel pin. The connector joint (**Fig 21**) will slide onto the top of the upper, vertical bar (**Fig 19**) and also fasten into place using a dowel pin. The user will then slide the top, horizontal bar (**Fig 22**) into the bracer bar (**Fig 20**) and connector joint (**Fig 21**) and be locked in place using a dowel pin. The patient's sling will be attached to the end of the top, horizontal bar (**Fig 22**) using a bolt, a generic attachment bar, and hooks. Finally, the user will slide the two battery packs and the motor onto their designated positions on the base of the frame (**Fig 15**). In

order to deconstruct the device, the user will perform these steps in reverse and in the opposite order and store the pieces in the provided carrying bag.

For the lifting mechanism, the power screw system is built as follows: There will be a piece (**Fig. 23**) that is welded to and fits flush with the inside of the lower, vertical bar (**Fig 18**). That piece has a hole in the center of it to house the gear shaft (**Fig 24**). At the internal end of the gear shaft, there will be a worm gear attached (**Fig 25**). The worm gear will be attached to a 1.25-inch-diameter, 3-inch-long rod (**Fig. 26**), which will then be attached to the 24-inch-long ACME lead screw. The screw is a Class 2G, 1 ½ inch - 4 lead screw. On the lead screw, there will be a platform with a hole cut through the center. The edges of this hole will be threaded to fit the lead screw. This platform will raise and lower as the lead screw rotates, and the upper vertical bar will sit on top of it. On either end of the power screw, there will be a nut welded in place to prevent the removal of the platform. The worm that is paired to the worm gear will be attached to the end of the motor shaft. The worm to worm gear torsional ratio is 1:20.

The extended height of the frame will be 77.3 inches tall, while the lowered height will be 53.3 inches tall. The base dimensions are 56.5 inches by 30 inches when the legs are square and 95.7 inches wide when legs are splayed. The patient will sit approximately 24 inches from the vertical section of the frame.

Figures 15 - 28: Parts with Dimensions

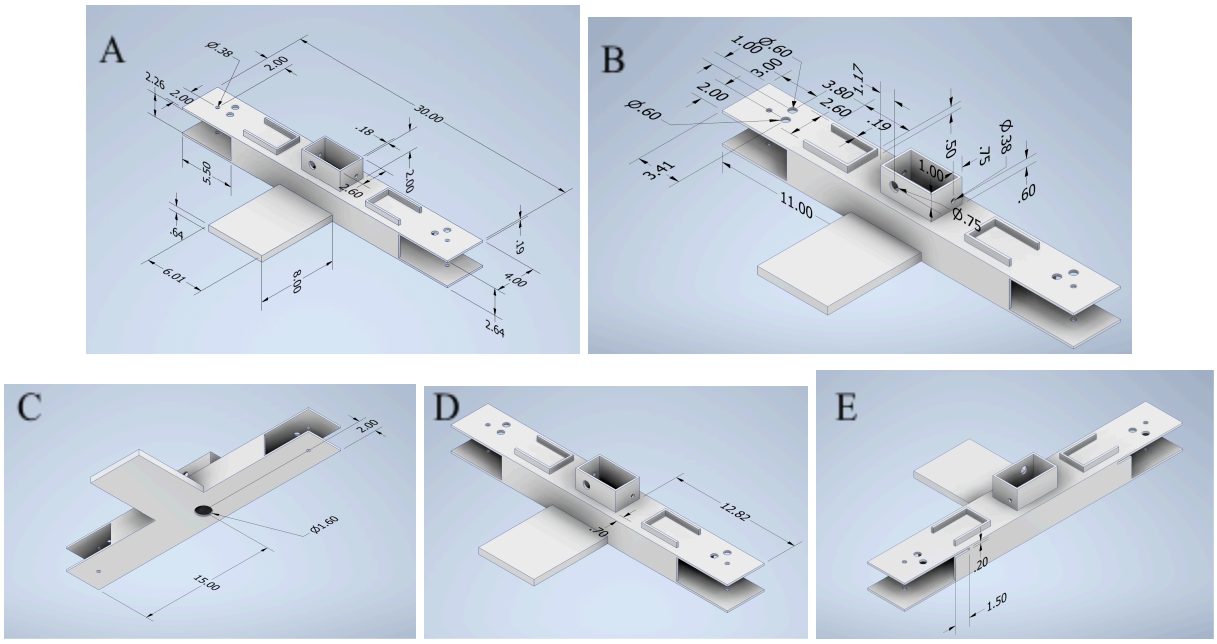


Figure 15: *Base Piece. Inventor Drawings by Lydia Miller and Jacob Schwartz. All dimensions are in inches.*

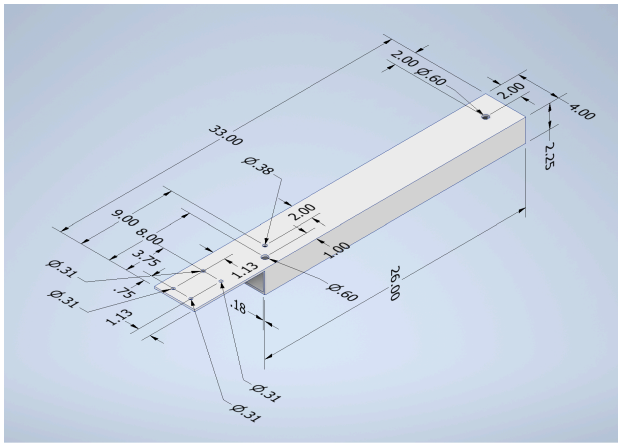


Figure 16: *Main Leg Piece. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches. This part is mirrored to make up the other main leg piece. Wheel will be attached to the extruding section.*

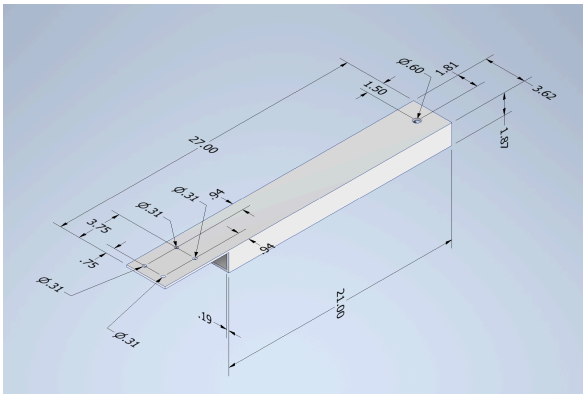


Figure 17: *Leg Extension Piece. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches. Wheel will be attached to the extruding section.*

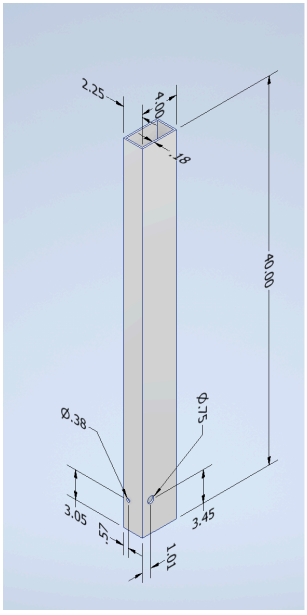


Figure 18: *Lower vertical Bar. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches.*

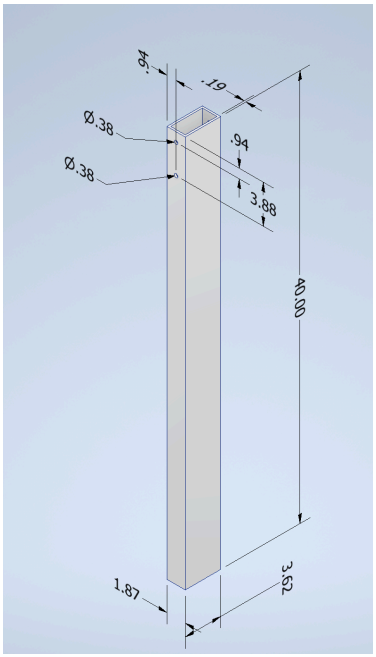


Figure 19: *Upper Vertical Bar. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches.*

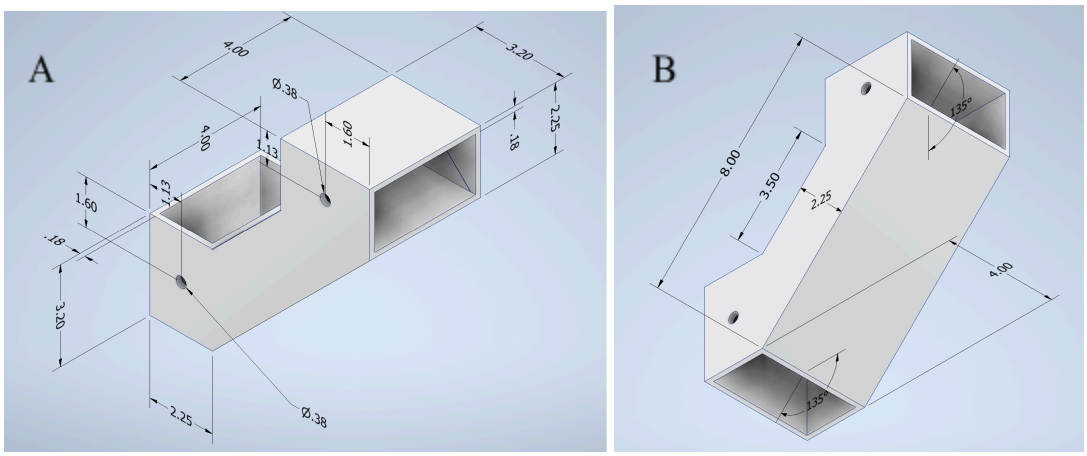


Figure 20: *Bracer Bar. Inventor Drawings by Lydia Miller and Jacob Schwartz. All dimensions are in inches.*

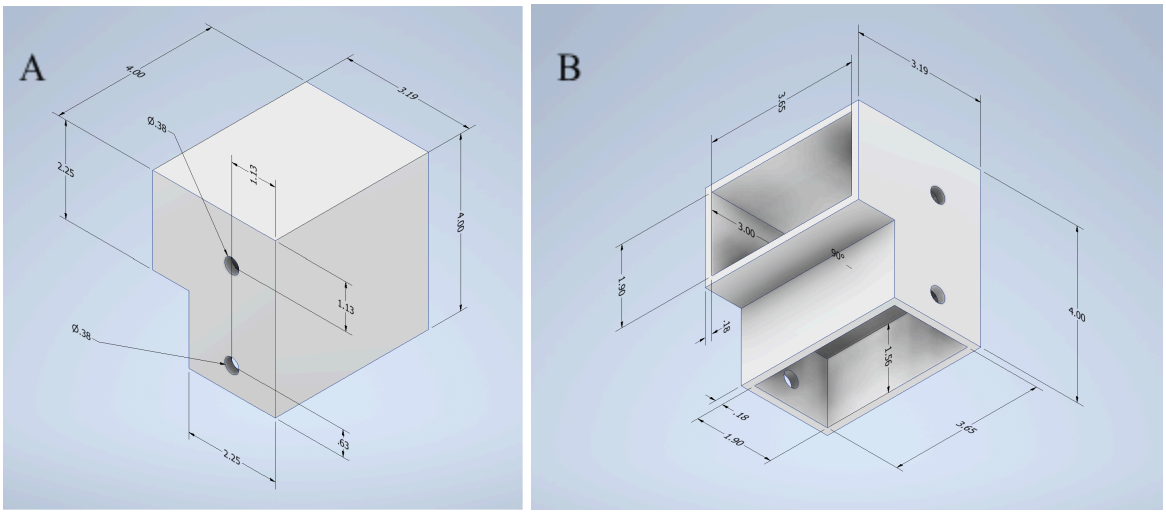


Figure 21: *Connector Joint. Inventor Drawings by Lydia Miller and Jacob Schwartz. All dimensions are in inches.*

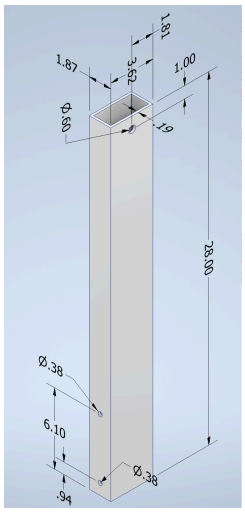


Figure 22: *Top Horizontal Bar. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches.*

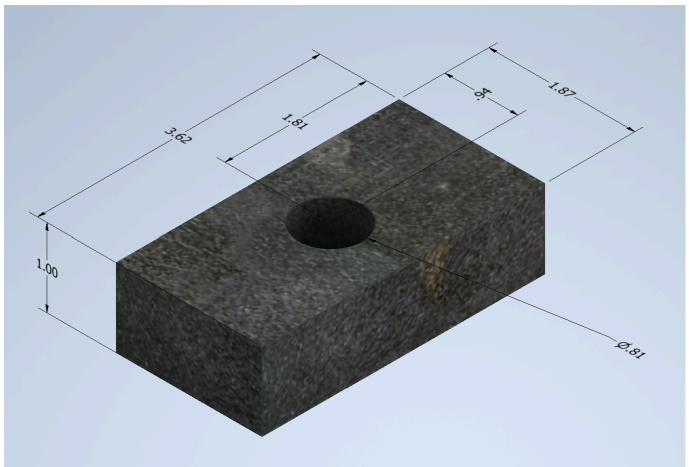


Figure 23: *Attachment Piece. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches.*

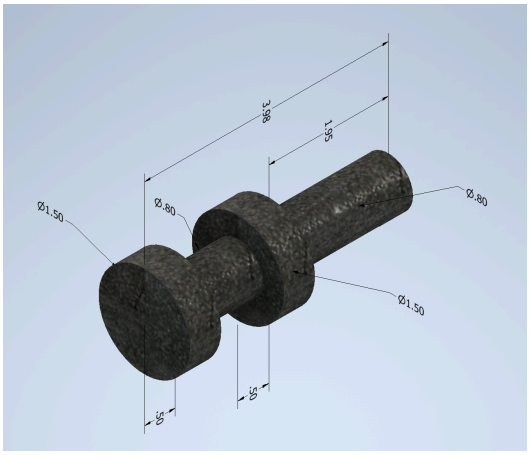


Figure 24: *Gear Shaft. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches.*

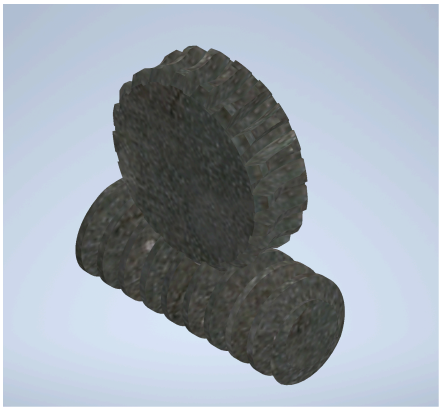


Figure 25: *Worm and Worm Gear. Inventor Drawing by Lydia Miller and Jacob Schwartz. The worm to worm gear torsional ration is 1:20. The diameter of the worm gear is 1.8 inches and the height is 0.6 inches. The length of the worm is 2.36 inches.*

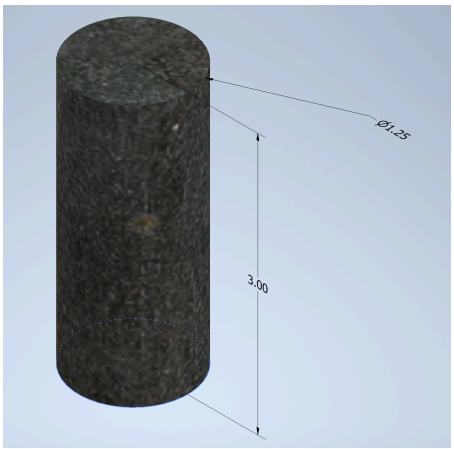


Figure 26: *Power Screw Attachment. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches.*

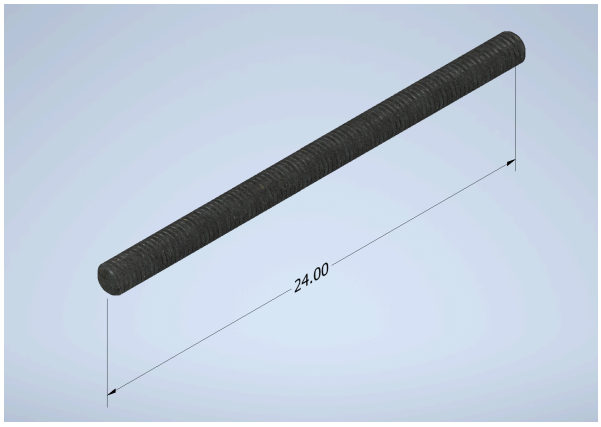


Figure 27: *Power Screw. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches. The lead screw is a 1 ½ inch 4 ACME Class 2G lead screw.*

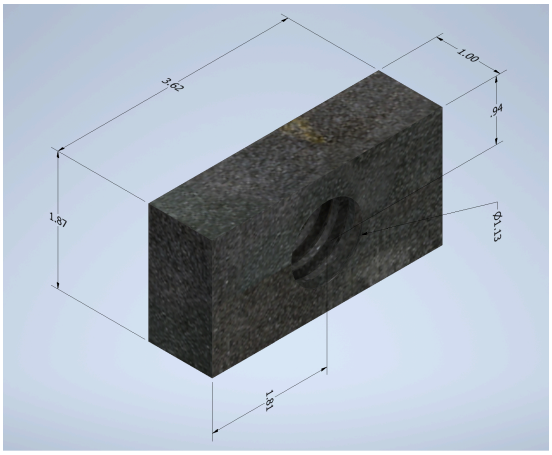


Figure 28: *Power Screw Platform. Inventor Drawing by Lydia Miller and Jacob Schwartz. All dimensions are in inches. The inside edges of the hole are fit to the lead screw.*

Design and Development Plan Summary

The design and development plan (Appendix C) includes brief descriptions of the problem to be solved, the needs statement, the literature review, the prior art search, the value proposition, the materials, the features, the components, and the current market for this product, as previously detailed. Furthermore, this plan prompted the team to determine that the device is a Class II Device as stated by the FDA, the reimbursement plan is to use a cost-based reimbursement strategy through insurance companies, and the estimated cost of manufacturing the device is approximately $973.84. This cost includes $32.69 in aluminum alloy, $12.24 for steel, $55 for the fabric sling, $133.90 for the sling cradle, $44 for locking wheels, $30 for pins, $24 for snap button locks, $63.03 for lead screw, $189.05 for the motor, $29.95 for the carrying bag, and $359.98 for 4 battery packs.

We have determined the following user needs:

1. **Patient and Caregiver Safety**
    a. The pin and socket system, the power screw system, and the lightweight of the product contribute to the assurance of safety for the patients and caregivers using the device.
2. **Affordable Price**
    a. By eliminating the need for multiple sling lifts, the amount spent by each patient is greatly reduced.
3. **Easy Operation**
    a. By using an electrical system powered by two battery packs and controlled by a button, the ease of operation is greatly increased.

4. **Portability from Bed, Car, etc.**
    a. Because the lift is capable of being collapsed and transported to numerous locations, it can be used for multiple situational purposes. This includes transport from bed to wheelchair, wheelchair to car, wheelchair to clinic seating, etc.
5. **Safe for Transport**
    a. Because the device is light, it is easy to lift in its collapsed form. Therefore, there is minimal risk to the caregivers who are transferring the lift into a car or different storage location.

Design Summary Matrix Summary

In the design summary matrix (*Appendix D*), the team determined design inputs, design outputs, verification activities, and validation activities for each user need.

User need 1: Patient and Caregiver Safety will be addressed through the use and implementation of various mechanisms throughout the device. A pin and socket system will be used to attach the different pieces of the device together to ensure they are locked in place during use and can also be safely and easily taken apart when the device needs to be collapsed for transport. Another mechanism to address this user need will be through the use of a power screw system for the actual lifting mechanism. This power screw system will ensure safe and stable lifting and lowering of patients and will ensure a very low device failure rate. Lastly, we will address this user need through the use of lightweight materials, such as aluminum, and using hollow rods to prevent excessive additional weight. Not only is it important for this device to be strong enough to lift the patient without failure, but it will be important for the caregiver to be able to disassemble, reassemble, and move the device without too much hassle.

User need 2: Affordable Price will be addressed through the expansion of the device's capabilities. Some patients require multiple different lifts, as they do not have one lift that can perform multiple functions. Further, many patients do not have a device that is capable of being transported during travel. Our device helps lower the overall cost for these patients by combining the capabilities of multiple devices into one singular lift.

User need 3: Easy Operation will be addressed through the use and implementation of an electrical system that will power the lift. This device will be powered by four removable and rechargeable battery packs. These battery packs will control the mechanism that will screw and unscrew the lifting mechanism as mentioned in User need 1, without the need for any physical

exertion by the caregiver. These battery packs will be controlled by a button with ease, thus reducing the difficulty of operation.

User need 4: Portability from Bed, Car, etc. will be addressed by the collapsible aspect of the device. Due to the foldable, collapsible nature of the device, it can be easily disassembled for transport. This means the device can be taken to multiple locations and used for multiple purposes, which include, but are not limited to: bed to wheelchair, wheelchair to car, wheelchair to clinical setting, or wheelchair to bathtub. This also allows for the device to be stowed when it is not in use.

User need 5: Safe for Transport will be addressed by using a light, yet durable, aluminum-alloy 6061 frame for the device. All of the bars in the device will also be hollowed, to help further reduce the excessive weight of the device without compromising the structural integrity. Since the device will be lightweight, there is minimal risk to the caregivers that are transporting the collapsed device into or out of a car or other storage location.

Design Review Meeting Summaries

The team met with Troy Drewry on November 30, 2023 to discuss the progress of the project and future steps to better the device. In this meeting, Troy Drewry provided the team with suggestions for changes to our completed documents at that point. We accepted these changes and revised all previous documents the same day for submission at the end of the semester (December 8, 2024). Mr. Drewry supported our design at that point and provided additional advice as we were beginning to create the CAD drawing of the product.

The team met with Troy Drewry on March 28, 2024 for our final design meeting. During this meeting, Troy Drewry provided helpful suggestions to improve our completed documents. We accepted these changes and revised all previous documents to match his suggestions. These suggestions were helpful in ensuring that all information about our design is included and clarified. Troy Drewry supported our documents after these changes and approved our final submission.

Risk Management Plan Summary

Risk management is a crucial aspect for companies to consider when developing devices that will be used in the medical and private sectors. Not only is it ethically crucial to consider the potential risks that could be endured by both patients and caregivers, but the Food and Drug Administration (FDA) sets in place strict regulations that prevent devices from going on the market that do not meet the safety guidelines. In order to minimize the potential risks our device could pose to patients and caregivers, we developed several precautionary measures and policies, such as the following:

1. **Develop an instructional manual and video for our device.**

The first control involved developing both an instructional manual and information packet for the device which would include step-by-step instructions along with images for the device. This guide would instruct the caregivers on how to properly use the device so that the patient can be safely raised and lowered. Additionally, this instruction manual would detail how to collapse the device for storage or for transportation purposes. In addition to the instruction manual, we plan to create an informational video. In this video, there will be step by step instructions on how to properly operate the device. We feel it is essential to not only provide a detailed instruction manual with pictures but also a detailed step-by-step video on how to operate the device in real time. This is also beneficial because if the device does not operate for the caregiver as it should operate in the video, then the caregiver will be able to contact support to find out more information before potentially putting themselves and the patient in harm's way. Furthermore, these precautionary measures ensure that improper usage does not occur.

2. **Place warning labels on the device.**

Though we would provide a very informational safety guide in the instruction manual and the video, we also feel it is crucial to include warning labels on the device. By including these labels, if someone, other than the caregiver, needs to operate the device without watching the video or reading the informational packet, they will be capable of safely doing so. Along with this, we plan to place warnings that detail how to avoid injury for both the patient and the caregiver, as well as various warnings about the weight and height limitations of the device.

3. **Implement required routine inspections/maintenance of the device.**

Like most medical devices that are in regular use, it will be crucial to set routine inspections in place for the device. The main reason for these routine inspections is, first and foremost, to ensure the safety of both the patient and the caregiver. Another reason that these inspections are so vital is because, though we plan to manufacture the device to the best quality possible, wearing on the device will still occur with repeated use. For heavier patients, the device will wear faster than it will for lighter patients. Additionally, it is important to keep in mind that the device will also wear faster if the equipment is used improperly. The average lifespan of a sling lift device is roughly three to five years, and we want to ensure that both patients and caregivers are safe throughout the entire lifetime of the device (Adaptive Specialties). Furthermore, routine maintenance will be required for the device. The rechargeable lithium battery packs can withstand 300-500 charge cycles before needing to be replaced (Renogy). Along with this, routine lubrication of the gears will be required to maintain proper function of the device.

4. **Perform quality control tests during the manufacturing process.**

During the production of the device, we will perform routine quality inspections to ensure that the quality of the materials and components that we are using for the device is maintained

and meets/exceeds the necessary specifications. We will do everything possible to ensure that no products containing defects are sold or put to use. Without strict quality control protocols, our product would have the ability to malfunction in a way that is not only detrimental to the patient, but detrimental to the caregiver as well. By reducing the potential for these unpredictable defects, we will be able to ensure that all customers are obtaining a device of a very high quality. Additionally, since our device qualifies as a Class II device by the Food and Drug Administration's (FDA) standards, it is crucial to have routine inspections of all of the equipment before these devices are given to customers.

The team's original *Risk Management Plan Form* is shown in Appendix G

Failure Modes and Effects Analysis (FMEA) Summary

In order to evaluate the risks associated with our product and develop a plan to manage these risks, we performed a Failure Modes and Effects Analysis (FMEA). The specific aspects of our device that possess the potential to cause harm are as follows:

1. **Material degradation and wear.**
    a. Our device will need to be able to lift and lower patients multiple times without failure throughout the device's lifetime.
    b. Our device must be able to withstand being taken apart and folded as well as being put back together multiple times throughout the devices's lifetime.
2. **Device failure.**
    a. The battery packs will need to be able to provide sufficient power to operate the device and to lift and lower the patient.
    b. The button will need to be fully operational without fail.
    c. Portions of the device will have to withstand different forces, and will need to be tested in multiple different ways before being used by caregivers or patients.
3. **User error.**
    a. Improper use of this device may cause harm to patients using the device or to the caregivers operating the device.
    b. Using this device incorrectly could lead to faster wear of the device and a shorter overall lifetime of the device.
    c. The use of this device for patients outside of the height and weight range could lead to harm of the patient or the caregiver operating the device.

Table 1: Severity Rating

Severity (SEV)		
Ranking	**Definition**	**Effect**
5	Catastrophic	Device failure or defect may cause death or permanent injury with or without warning of failure
4	Severe	Device failure or defect will cause severe injury which would necessitate revision surgery
3	Moderate	Failure renders device useless or will result in a minor injury of a non-permanent nature
2	Minor	Failure will result in no loss of product performance but may create some annoyance to user
1	None	No effect

Table 1: *This table displays the severity of each potential harm by assigning a severity rating. High rankings indicate potential harm that may be severe to users. A low severity rating means that there would be little to no effect on the patient or caregiver meanwhile a high score would be indicative of a very harmful event occurring. This table was used to calculate the Risk Index of the device failure (shown in* ***Table 3****). This table was provided by Troy Drewry.*

Table 2: Occurrence Rate

Occurrence (OCC)		
Ranking	**Definition**	**Frequency**
5	Extremely High	Failure almost inevitable
4	High	Repeated failure
3	Likely	Occasional failure
2	Rare	Failure unlikely
1	Remote	Remote chance of failure

Table 2: *Document the probability of occurrence of each harm. A low occurrence rate indicates that there is a small likelihood that the device will fail, whereas a high occurrence rate is indicative that device failure is inevitable. This table was used to calculate the Risk Index of the device failure (shown in* ***Table 3****). This table was provided by Troy Drewry.*

Table 3: Risk Index Table

Risk Index Table							
			Hazard Severity Level (SEV)				
			None	Minor	Moderate	Severe	Catastrophic
			1	2	3	4	5
Occurrence (OCC)	Extremely High	5	5	10	15	20	25
	High	4	4	8	12	16	20
	Likely	3	3	6	9	12	15
	Rare	2	2	4	6	8	10
	Remote	1	1	2	3	4	5

Table 3: *This table shows the potential Risk Indices of certain device failures based on their Hazard Severity Level (SEV) from* ***Table 1*** *and their Occurence (OCC) scores from* ***Table 2****. Evaluate the risk level. If everything is green or yellow, the device is satisfactory. This table was provided by Troy Drewry.*

The Risk Index Table displayed in **Table 3** shows the risk indices of given failures based on two factors: Severity (SEV) and Occurrence (OCC). **Table 1** displays the severity rankings of particular failures based on the danger they pose or harm they have the potential to cause to the patient or caregiver. The scale ranges in scores between 1, which implies “no effect” on the patient or care provider, and 5, which is indicative of a failure that has the potential to cause “death or severe injury with or without warning of failure”. **Table 2** displays the frequency rankings of particular failures based on how often they are likely to occur. The scale ranges from a score of 1, which is indicative of a “remote chance of failure”, to a score of 5, which implies that “failure is almost inevitable”. These scores are multiplied for each possible risk associated with the device to obtain a risk factor number from **Table 3**.

1. **Wheels**

    a. *Failure to lock in place*

    Should the wheels fail to lock into place, the device would become very unstable and dangerous to use. There would be potential for the device to move while it is being used to lift and lower the patient. This would not only be dangerous for the patient, but it would be dangerous for the operator as well. This could cause harm to both parties and could lead to device instability. While these wheels may be unlocked for movement after the patient has either been successfully lifted or successfully lowered and removed from the sling, the wheels should not be unlocked during the act of lifting or lowering. The team assigned this risk a severity rating of 3 and an occurrence rating of 1, for a risk index of 3.

    b. *Falling off/ being knocked off*

    During transport of the device, there is potential for the wheels to be knocked off or fall off if the wheels are not properly stowed in the bag. If one or more wheels are knocked off of the device, it will make the device unstable for use, as the device will not be able to securely and effectively maintain a level, upright position for use. Additionally, if one or more of the wheels were to come off during use, this would be detrimental to both the patient and the caregiver and would have the potential to cause a great deal of harm to both parties, as the device would be knocked over. The team assigned this risk a severity rating of 3 and an occurrence rating of 1, for a risk index of 3.

2. **Battery failure**

    a. *Failure to lock in properly to provide sufficient power*

If the battery packs fail to lock into place to effectively provide power, the device would be rendered useless, as it would not be able to lift or lower the patient effectively. Due to the fact that this is a low risk problem, the team assigned this risk a severity rating of 1 and an occurrence rating of 1, for a risk index of 1.

b. *Diminishing battery life*

Following prolonged and repeated use of the battery packs, the power that they provide will diminish. These batteries have to be regularly charged. If the batteries are not charged, the device will cease to work, potentially in the middle of operation. Due to the low risk nature of this issue, the team assigned this risk a severity rating of 1 and an occurrence rating of 1, for a risk index of 1.

3. Hooks

a. *Hooks breaking loose during use*

If one or more of the hooks were to break during use, the patient would fall to the ground. This could cause injury. The team assigned this risk a severity rating of 4 and an occurrence rating of 1, for a risk index of 4. The team determined that this risk would occur extremely infrequently as manufacturing quality control processes would be in place to prevent this from happening.

4. Collapsible aspects

a. *Device collapsing during use*

If one or more of the collapsible components of the device were to engage while the patient is in the sling, injury could occur. Fortunately, based on our design's use of pin and socket systems, this is highly unlikely to occur. Therefore, the team

assigned this risk a severity rating of 4 and an occurrence rating of 1, for a risk index of 4.

5. Material failure

a. *Screw system failure*

There is potential for the power screw system that allows for the lifting and lowering of the device to fail. This could occur if the battery packs fail to produce the power necessary to engage the motor to rotate the power screw. In order to keep the screw from rotating when power is not supplied, a worm and worm gear system has been utilized. The team assigned this risk a severity rating of 3 and an occurrence rating of 1, for a risk index of 3. Failure of the power screw system could also occur due to thread shearing. Overtime, the screws and rods will experience wear. If this wear is significant enough, the screw may slip into the rod, without the user's intent, causing the height of the device to be immediately reduced to its minimum. If a patient was to be inside of the sling during this event, the patient may become injured. To combat this, users must follow their instruction manual and replace their lift after the indicated lifetime of the device. The team assigned this risk a severity rating of 3 and an occurrence rating of 3, for a risk index of 9.

b. *Device material wear*

The device, which is mainly made of aluminum 6061, will experience wear over time. If this wear is significant, the device may fail to operate properly. Potential injury could occur following failure. To avoid this issue, users must maintain a regular inspection schedule and ensure that the device is being used properly. The

team assigned this risk a severity rating of 4 and an occurrence rating of 1, for a risk index of 4.

c. *Storage Bag Material Wear*

The device will come with a carrying bag so that it can be easily transported or stored when the device is not in use. The bag will have a strap/straps on it so that the caregiver will be able to safely transport the device either to storage or another location, such as a car, if the patient and the caregiver are traveling. Through routine quality inspections, the quality of the bag will be ensured before distribution to customers. The team assigned this risk a severity rating of 2 and occurrence rating of 2, for a risk index of 4.

6. **User error**

a. *Improper use of device*

If the device is utilized in a manner that is inconsistent with the intended use, possible injury may occur. All users of the device must refer to the instruction manual which outlines warnings for misuse and step-by-step instructions on how to use the device properly. The team assigned this risk a severity rating of 4 and an occurrence rating of 1, for a risk index of 4.

b. *Patient is not within height range*

If the patient's height is over 6'5, sufficient head clearance will not be provided. The vertical bar is only tall enough to fully lift a patient that is at or below the height of 77 inches, so if a patient that is above this height is lifted, there is a chance that the patient could hit their head. This team assigned this risk a severity rating of 2 and an occurrence rating of 2, for a risk index of 4.

c. *Patient is not within weight range*

If the patient is over 350 lbs, the polyester fabric sling will not provide the necessary support. The sling itself may rip, or the straps of the sling may tear. This could lead to the patient falling to the ground and becoming injured. Thus, patients should refer to the weight limitations listed on warning labels on the device itself, information from the instruction manual, and the informational video. The team assigned this risk a severity rating of 4 and an occurrence rating of 1, for a risk index of 4.

d. Overturning of the device

Although the counterweight of the base provides effective stability while the lift is in use, the device is still capable of being tipped over if not used properly. For example, if an individual was to swing back and forth while in the sling of the device, injury could occur due to the lift overturning. The team assigned this risk a severity rating of 4 and an occurrence rating of 1, for a risk index of 4.

The team's original FEMA form can be found in *Appendix I*.

Verification and Validation Plan Summary

Our team's verification and validation precautions are discussed previously in the Design Summary Matrix Summary section, though this section outlines and details our precautionary measures more specifically.

Our plans for device verification include:

1. **Mechanical testing and durability checks.**
    a. To further test the limitations of our product for safety measures, we will perform mechanical stress tests on our device.
    b. This will account for user need 1 and user need 2.
2. **Quality checks and routine inspections.**
    a. To ensure the quality of our device, we will conduct very strict, dynamic quality testing and checks to verify that our device parts were assembled using the correct dimensions and that they are capable of both being assembled and disassembled correctly before their distribution.
    b. This will account for user need 1 and user need 5.
3. **Ease of use checks.**
    a. As our device is specifically marketed to be easy to use, we will perform ease of use checks to ensure that the device is able to function properly without strain on the caregiver.
    b. Some of these checks will include making sure that the batteries are easy to replace and charge, the device can be assembled and disassembled properly, and that the device can be folded and placed within the storage bag for transport or storage.

c. This will account for user need 3.

These verification plans will ensure that our device is user-friendly, safe, functional, and compatible with our patient population's needs.

Our validation activities will include:

1. **Visual inspections and quality checks of the device**
    a. In similar fashion to the verification plans detailed above, conducting visual inspections and quality checks of the device before its distribution will ensure that customers will receive a quality product that functions as intended.
    b. This will account for user need 1, user need 3, and user need 5.
2. **Further testing the device in clinical and residential settings**
    a. To ensure that our device is able to withstand the strains of everyday use, the device will be tested in controlled residential and clinical environments before being placed on the market to ensure that there are no additional modifications that need to be made to the product before it is distributed to customers.
    b. This will account for user need 1, user need 3, and user need 4.

Gillespie Business Plan Competition Summary

Our team entered the Gillespie Business Plan Competition on March 21, 2024, under the team and company name “MLLM Innovations” as part of our senior design project with the following logo:

Our team’s idea was the ATLAS, an acronym for A Transportable Lightweight Affordable Sling lift. Our company, MLLM Innovations, has a goal of helping to mitigate the difficulties of transportation for partially or totally immobilized patients by developing products that expand upon the capabilities of devices currently on the market. We do not currently have a patent, but we plan to obtain one in the near future. Once obtained, we would plan to market our product using online vendors, including various medical device distribution websites so that we could target assisted living facilities, long term care facilities, and home care services. We would also make pamphlets to be distributed from hospitals and buy advertisement space in health magazines for additional customer exposure to our device. To more effectively reach and train caregivers and other health care professionals to use our device, we would specifically target assisted care facilities as the initial customer of our device. In this way, caregivers could aid patients using our device and, once they determined that our device was easy to use and highly effective, would be able to recommend our device to other caregivers and to those living with mobility issues. This will eventually allow us to reach into the general population portion of the

sling lift market. Our product, the ATLAS, will be priced at $2,000, which is very competitive in the current market, where devices can reach prices up to $20,000. Our team competed in the competition on April 12th, 2024.

Future Works

Over the past several months, our team rigorously worked on the development of ATLAS, ensuring that the final product would be ideal for the market we are attempting to enter. Before ATLAS enters the market to be purchased by customers, it will undergo rigorous testing in various areas, as detailed previously (*See Verification and Validation Summary*). Also, we plan to develop a manual that details exactly how to use the device along with the patient height and weight requirements in order to ensure safe and effective use of our device. Additionally, we plan to create a video that will demonstrate how to use our device in real time, offering more information to both patients and caregivers that plan to use our device.

Following the market launch of the product, the company plans to expand upon the mission of providing immobilized patients with devices that aid in their transport. This includes producing unique walkers, wheelchairs, crutches, and more. Furthermore, the company plans to create products that can be used in conjunction with the ATLAS lift.

<u>Wheelchairs</u>

The electric wheelchairs currently on the market present numerous issues. Firstly, many of the wheelchairs are tall, wide, and heavy which impairs the ease in which the wheelchair can be put into a vehicle. Furthermore, because the wheelchairs are large, they often cannot fit underneath tables. This impairs the patients' ability to function normally in a home, restaurant, or professional setting. To combat this, the team plans to create a wheelchair that is made of light material and is capable of lifting and lowering the patient's seating position.

Along with this, the team plans to design a wheelchair that has ample storage space. This will not only aid in the transport of personal or medical items with the patient, but it will also be capable of carrying the collapsed ATLAS lift with the patient. Many electric wheelchairs are

controlled by a joystick that is designed for the patients themselves to use, but in many cases, the patients are not capable of accurately steering the device. This leads to the caregivers manipulating the joystick while walking alongside the wheelchair. The team recognizes that because of this, it would not be ideal for the caregivers to carry the bag containing the collapsed sling lift while performing this task. Therefore, by creating an electric wheelchair with ample storage, the sling lift is capable of being transported without manual carrying by the caregivers.

Also, the team plans to create a standard, non-electric wheelchair that provides the necessary storage space for the collapsed version of the lift.

Walkers

Similarly, many walkers do not provide sufficient storage space for the users' needs. These patients do not typically require a sling lift for transport, yet they do need to use their hands to operate the walker. Because of this, they rely on the storage in their walkers to carry their personal belongings. The team plans to create a walker that provides an ample amount of storage space such that users can house all their personal belongings for simple transportation.

Crutches

Crutches tend to consume a large amount of space. This becomes an issue when the users are confined to small areas, such as within a car or on a plane. To combat this issue, the team plans to create crutches that are collapsible. Ideally, the crutches will be capable of being reduced to nearly ⅓ of their extended length. This will allow the crutches to be easily stored while the user is not using them. For example, they can be stored in the overhead compartments on planes without hassle or on the floorboard of a car without restricting leg room.

Appendix A

BACKGROUND

- **Summary:**

  The first sling lift, commonly known as the Hoyer lift, was created between 1940 and 1950 by a quadriplegic man named Ted Hoyer. Ted was an quadriplegic innovator whose frustration with his lack of independence and mobility inspired the draft plans that ultimately led to the formation of the first powered patient lift. Since their creation, mobile patient lifts have undergone many new developments and innovations to enhance their use. Sling lifts are often used to transport patients from one place to another. In most cases, this is from the bed to a wheelchair, but more recently, collapsible/portable sling lifts have become more popular as the demand for easy transport to and from doctor appointments and personal events has increased. There are numerous types of hoyer lifts on the market including power hoyer lifts that feature an electric motor, manual hoyer lifts that feature a hydraulic pump system, sit-to-stand hoyer lifts that rely on the patients pulling themselves up, and ceiling hoyer lifts that include a track on the ceiling to carry the patients across rooms, into different parts of the house, medical facility, etc.

- **Search Terms:**
  - History of the Hoyer Lift
  - Collapsible Hoyer Lift Background

- **References:**
- https://www.assistedliving.org/best-hoyer-lifts/
- https://www.handimove.com/blog/history-of-the-mobile-patient-lift-or-steel-nurse#:~:text=The%20first%20mobile%20patient%20lift,the%20Hoyer%20hoist%20(%3D%20lift).
- https://macdonaldshhc.com/wp-content/uploads/2015/02/Hoyer-Lift-Brochure.pdf

CURRENT TREATMENT OPTIONS

- **Summary:**

  While there are a few collapsible, portable hoyer lifts on the market, many of them are very expensive. With the majority of current options having a sticker price between fifteen hundred and ten thousand dollars, the high cost of these devices limit the accessibility to the general public. The other drawback to many of these models is that the majority of them are not waterproof, meaning that if there is inclement weather, there could be a potential for damage to the device. Many of the cheaper hoyer lifts are also limited in terms of capabilities. Though portable, the range of motion is restricted so that lifts may only be used indoors rather than being used to lift patients in and out of cars as well. There are also customer complaints for the manual, cost efficient hoyer lifts, as they can be difficult to operate.

- **Search Terms:**
  - Portable Hoyer Lift
  - Collapsible Hoyer Lift

- **References:**

  - https://www.amazon.com/Advance-Portable-Hoyer-Patient-Electric/dp/B00PXD1ALW
  - https://www.rehabmart.com/product/molift-smart-150-patient-lift-35855.html
  - https://www.rehabmart.com/product/maxi-twin-mobile-patient-lift-47670.html
  - https://www.phc-online.com/Hoyer_Advance_E_Patient_Lift_p/hoy_advance.htm
  - https://ecaremedicalsupplies.com/patient-lifts/ilift-foldable-power-hoyer-lift-sling-included-450-lb-cap-30010007/

IDENTIFY USER NEEDS

- **Summary:**

  There are few portable slings lifts on the market currently, and they are extremely expensive, limiting market reach. Through research, it was found that prioritizing a low price often leads to an increased risk for safety. There are multiple cases in which sling lifts have collapsed (either the mechanical arm has broken or the sling itself has torn) leading to injury. Furthermore, caregivers are often getting pinched while folding and unfolding the lifts. Because of this, customers have voiced a simultaneous need for adequate safety and acceptable costs.

  Many operators have difficulties operating the lifts. This is due to either the presence of a complex protocol or inadequate training. Furthermore, many caregivers who use sling lifts are the spouses of elderly patients, thus typically making them elderly themselves. It is difficult for these caregivers to carry/transport portable lifts into and out of their cars, houses, etc.

  Therefore, there is a need for a portable sling lift that is relatively less expensive, safe for patients and caregivers, easy to operate, and light.

- **Search Terms:**
  - Needs for portable sling lift
  - Risks of portable sling lift
  - Hoyer Lift Safety
  - Hoyer Lift Breaking Cases

- **References:**
  - https://www.mn-nursinghomeabuse.com/injuries-from-mechanical-lifts-in-nursing-homes/
  - https://www.krasnolaw.com/blog/hoyer-lift-flaws
  - https://dhs.sa.gov.au/__data/assets/pdf_file/0006/89529/SWI-OCC-016-2013-Use-of-a-Portable-Hoist-to-Lift-a-Person-from-the-Floor.pdf
  - https://www.101mobility.com/products/patient-lifts/portable-patient-lifts/
  - https://mdaquest.org/portable-lifts-real-pick-me-caregivers/

MARKET RESEARCH

- **Summary:**

  The market already consists of many hoyer lifts, with a few foldable/deconstructable lifts that are usually quite expensive. This cost seems to mostly come from the cost of the hydraulic pump used to operate the lift. The market potential for our product would be to find a way to create a portable lift that costs as much as the non-portable lifts. Another complaint with the current market is that while the lifts are portable, they still are quite heavy and a pain to carry around. The other market opportunity for our product would be to find a way to reduce this weight while still providing enough counterweight to function as a lift. Lastly, all of the current portable lifts usually include a part that folds and a part that needs to be detached. The last market opportunity with our product could be to find a way to make the process of "folding" the lift easier to not take as much time (currently about 3-5 minutes to fold or unfold the lifts on the market depending on the product) and to make the product overall more accessible.

- **Search Terms:**
  - Foldable Hoyer Lift
  - Portable Hoyer Lift
  - Cost of Hydraulic Pumps

- **References:**

  - https://www.amazon.com/Advance-Portable-Hoyer-Patient-Electric/dp/B00PXD1ALW
  - https://www.amazon.com/Hi-Fortune-Electric-Hydraulic-Portable-Adjustment/dp/B077YHZGQ2?source=ps-sl-shoppingads-lpcontext&ref_=fplfs&psc=1&smid=ATVPDKIKX0DER
  - https://www.jeepumps.com/hydraulic-pumps-a-complete-overview/#:~:text=Higher%20Cost%3A%20Hydraulic%20pumps%20can,cost%2Deffective%20for%20smaller%20systems.
  - https://medmartonline.com/patient-lifts/folding-portable-lifts

COMPETITIVE LANDSCAPE

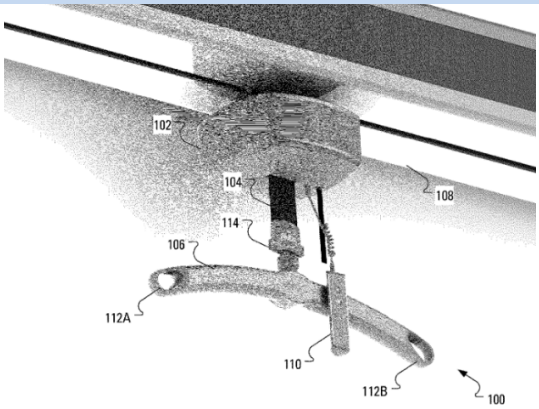
- **Summary:**
  The market is filled with various companies that produce Hoyer lifts and similar products for the mobility of people who don't have it on their own. Each of these companies have their own strong suits. The one that is considered the best is called Joerns Healthcare. They are the oldest and have the patent on Hoyer lift. Other companies have similar designs, but they aren't technically called Hoyer lifts. The design of the lift is meant to have intelligent positioning of the body for comfort and safety. Unfortunately, this company tends to be incredibly expensive, and the batteries don't last very long. Other companies, such as Bestcare and Invacare, have good lifts as well, however, the main complaints are that they are either expensive or they don't have every type of lift option imaginable. The main way these companies make the lift portable is by attaching wheels to the bottom and folding it in on itself. Complaints show that they are still really heavy and a pain to move despite being portable. The key learnings from this are that we would have some strong competitors in this market. Most of the designs are incredibly similar, so if we were to solve the problem in an innovative way, we could potentially break through the competitive landscape. We could hopefully solve some of these issues that other lifts have, such as weight issues, too.

- **Search Terms:**
  - Who makes hoyer lifts
  - Portable sling lift

- **References:**
  - https://macdonaldshhc.com/wp-content/uploads/2015/02/Hoyer-Lift-Brochure.pdf
  - https://www.caring.com/best-hoyer-lifts/
  - https://medmartonline.com/patient-lifts/folding-portable-lifts

Appendix B

Prior Art Reference #1 (US10555856B2 Patient Lift System)



- **Search Terms:**

  Hoyer Lift, Sling lift, Portable Sling Lift

- **Summary:**

The abstract states that the patient lift system includes a lift, a carry bar, and a hand control. The shapes of the bar and hand control facilitate quick cleaning and maximize infection control. This system includes a trolley for connecting the lift system to a track on the ceiling. The trolley and lift system are separate, yet can be easily attached or detached.

The background states that the known patient lift systems are typically designed to be attached to a track on the ceiling of a room. The track may also utilize electrical power. Yet, the size of the patient lift systems seem to be too large, especially for small rooms or rooms with low ceilings, and the shape of the known systems may not be advantageous.

According to the present disclosure, it is stated that there is a provided patient lift system for connecting to a track that includes a trolley that forms electrical and mechanical connections to the track. The system includes a lift unit chassis, a strap hub, a hub gear attached to the strap hub, gear shifts, gears, and motors. The hub gear rotates in response to rotation of the gear shafts by the motors. The system also includes a strap connecting to the lift unit chassis and a connector which is connected to a carry bar which allows the rotating hub gear to tighten or release the strap, raising or lowering the carry bar.

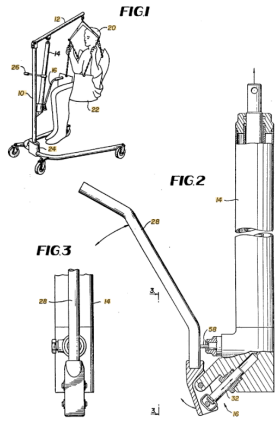
The Claims state that the the patient lift system is comprised of a trolley arranged to form a mechanical connection to a track, a connection member of the trolley, a lift unit chassis

consisting of a strap hub and a motor that is distinct from the trolley that forms a mechanical connection, a hub gear attached to the strap hub, a gear shaft, a motor gear mounted to the gear shaft, and a motor that drives the gear shaft.

- **Source:**

  Google Patents (https://patents.google.com)

Prior Art Reference #2 (*EP0000443B1 Hydraulic jack and patient lifting device*) *European Patent Office*



- **Search Terms:**

  Hydraulic patient lift

- **Summary:**

The Abstract states that the invention relates to hydraulic jacks consisting of a ram, a reservoir, a pump with a manual handle for drawing fluid from the reservoir, and a return valve to allow fluid to return from the ram to the reservoir.

The Background states that in prior devices employing hydraulic jacks, requiring the movement of the handle to operate the release valve presented difficulties. Furthermore, prior devices include an upright member/bar, a boom, a fluid cylinder or hydraulic ram, a fluid reservoir, and a manually operated pump used to force fluid from the reservoir to the chamber of the cylinder in order to raise the boom. In the past, to lower the boom, the operator either released the pump handle or used a separate hand to press a button. Either of these options are undesirable as convenience is limited.

The patent discloses and the claims state that the device is comprised of an upright member, a boom connected to the upright member, a hydraulic ram connected to the upright member and the boom, a manual pump, a fluid cylinder, a reservoir, a conventional sling chair suspended from the outer end of the boom, allowing rotation, a handle, a pumping piston, a transfer chamber, a loose pin that prevents the valve from moving above the opening of the pumping piston, and a spring. Furthermore, the transfer chamber is divided into an inner and outer chamber, there is a compression spring in the inner chamber that lends bias towards the closed position of the valve, a conduit that leads from the valve to the reservoir, and a plunger.

- **Source:**

  Google Patents (https://patents.google.com)

Prior Art Reference #3 (*US10610431B2 Lift System with Lowering Mechanism*)

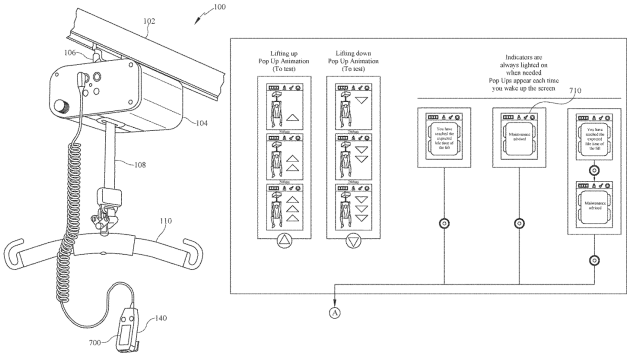


Figure 1. A perspective view of an exemplary rail-mounted overhead patient lift system, according to one or more embodiments described herein

- **Search Terms:**

  Hoyer lift, Sling Lift

- **Summary:**

The Abstract describes the lift system as an overhead patient lift system including a drum which is operatively coupled to a motor, which can rotate in either a clockwise or counterclockwise manner, alluding to the fact that the system is designed to both lower and lift patients.

The Background of the invention discusses how caregivers need a way to move patients from one location to another in a care facility or in a patient's home, and can require a lift system to assist with the process. While there are other products on the market that meet this need, the

background describes that there is room for improvement and, thus, a persisting need for further contributions in this technology.

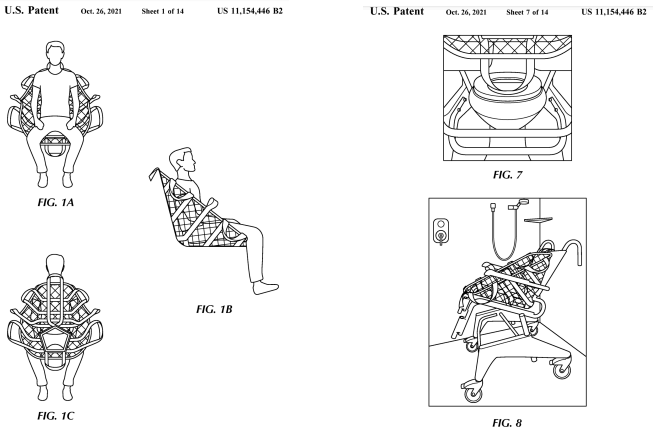
The Summary also describes the lift system as an overhead patient lift system including a drum which is operatively coupled to a motor, which can rotate in either a clockwise or counterclockwise manner, alluding to the fact that the system is designed to both lower and lift patients. The summary also describes the overhead patient lift system that includes a tail coupled support surface, a lift unit movably coupled to the rail by a carriage, and a movement system at least partially enclosed with the lift unit, a method for manually extending a lifting strap, and the transmission of electronic data signals.

The Claims state that the overhead patient lift system is comprised of an electric system that can receive, transmit, store, display, and process data that is input from outside stimuli, one or more of a lift motor, motor system, a movement system, and a brake system, visual alerting system, computer, and computer network.

- **Source:**

  Google Patents (https://patents.google.com)

Prior Art Reference #4 (*US011154446B2* Portable Transfer Chair and Lift)



- **Search Terms:**

  Portable hoyer lift, Portable sling lift

- **Summary:**

The Abstract describes the portable transfer chair and lift as a webbing configured to support at least the back and legs of the individual and a plurality of handles, configured for lifting the patient, around the webbing and weaved together to support the webbing.

The Background of the invention discusses that this product was developed to help people with physical disabilities such as Duchenne muscular dystrophy (DMD), amyotrophic lateral sclerosis (ALS), spinal muscular atrophy (SMA), and quadriplegia, and how, as adults, it can be difficult to help lift these individuals. The products on the market before the development of the "MegaMover" were too expensive, not portable, and not functional for going to the restroom or showering/bathing.

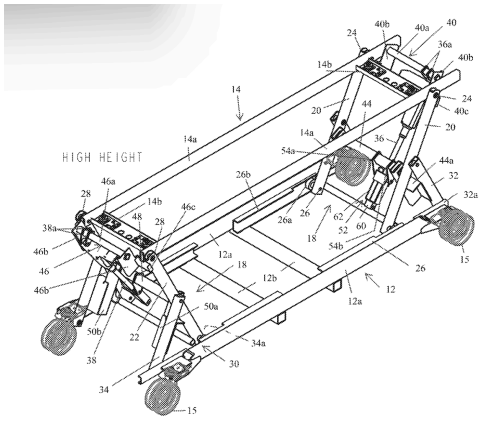
The Summary describes the "MegaMover" as a portable transfer sling for a disabled individual. The portable sling includes a webbing configured to support at least a back and legs of the individual, a plurality of handles around the webbing and weaved together to support the webbing, the handles configured for lifting the individual, and a plurality of loops stitched together with each handle of the plurality of handles. Additional features are made apparent in the detailed descriptions of the drawings included within the patent, such as waterproof materials and additional handles.

The Claims portion of the patent describes the "MegaMover" as a portable chair for a disabled individual comprising a webbing configured to support at least the back and legs of an individual, an intricate design of webbing, the plurality of handles for lifting the patient, with at least one handle in the front, one handle in the back, and at least two side handles. The design also includes a water resistant polypropylene webbing and buckles.

- **Source:**

  Lens.org (https://www.lens.org)

Prior Art Reference #5 (*US20160302985A1 Patient Support Lift Assembly*)



- **Search Terms:**

Collapsible hoyer lift

- **Summary:**

The Abstract describes the lift as having multiple frames, supported relative to the floor and for supporting the patient. It has a lift assembly for raising and lowering the patient. It includes extendible members and an actuator.

The Background describes the purpose of the invention is to raise and lower a patient to a height in which a caregiver may access the patient comfortably.

The Summary of Disclosure describes all of the features of the lift and its positions. It has one position in which the patient is able to be raised or lowered relative to the base. It has at least one leg in this position. The leg has at least an upper pivot point at the frame and a lower pivot at the base. It describes the connection points of each piece and the Y-shaped frame itself. There are spaced "webs" and cushion for the patient to sit in. There are also crank arms for controlling the hoist.

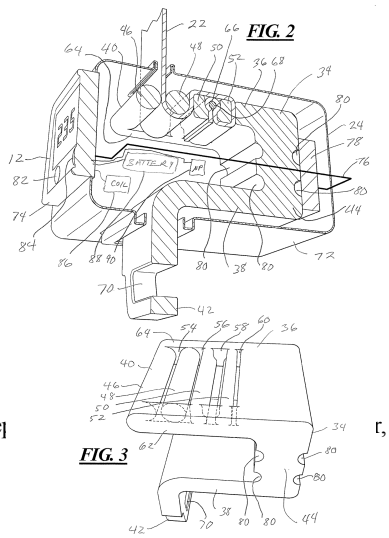
There was not a claims section explicitly stated in the patent.

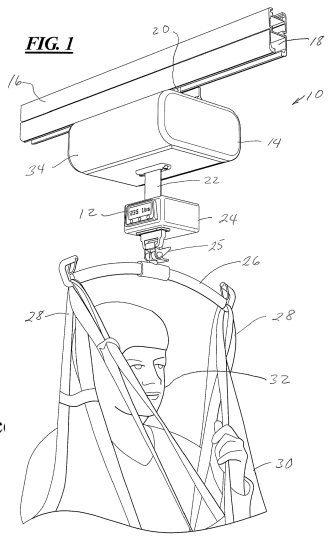
The Detailed Description explains each part in fuller detail, along with how the device folds to become portable.

- **Source:**

Google Patents (https://patents.google.com) (Link)

Prior Art Reference #6 (*EP2862552B1 Sling Bar or Lift Strap Connector having an Integrated Scale with Tilt Compensation*) European Patent Office





- **Search Terms:**

  Hoyer Lift; Portable Patient Lift System

- **Summary:**

The Abstract states that this invention is a type of scale to be used with overhead patient lifts (and hydraulic patient lifts to a lesser extent) to provide a means of measuring the weight of the patient without reducing the available lift height of the patient.

The Background of the Invention discusses how patients that are confined to patient lift systems, often are not able to stand on their own to weigh themselves on a scale. The idea of an "in-line scale" connected in between the lift system and the patient sling has been thought of before, however, previous inventions had drawbacks which limited their functionality. Most notably, by placing the scale between the patient and the lift, the distance between the two will grow as the line now has this extra slack created by the scale. This extra slack could make it to where a patient is unable to fully be lifted off of a bed or chair, unable to get an accurate weight measurement.

The Summary of the invention is described as an integrated scale within the sling bar of the patient lift system. By having the scale integrated into the actual design of the lift, the height loss associated with the "in-line scale" is eliminated, gaining back the 6 inches or more of lift height that was lost this way. The integrated scale is also configured to be able to function regardless of the angle tilted from the horizontal. Because patients who use lift systems often cannot move themselves, keeping them directly vertical with the system to allow no tilt is virtually impossible to get an accurate weight measurement. This integrated scale overcomes this by constantly measuring the angle at which it is positioned and being able to calculate the weight to display the most accurate measurement regardless of position of the suspended load.

The Disclosure and Claims section both describe how the integrated scale is part of the a patient lift system, integrally connected with the sling bar attached to the lift strap and hooked up to a power source to provide power to the scale/load cell. The sensor and load cell are configured with a processor to calculate the weight of a load suspended from the sling bar regardless of tilt angle from the horizontal.

- **Source:**

  Google Patents (https://patents.google.com)

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F01, Version B Design and Development Plan

Project Name: Collapsible Sling Lift	DHF # 2	D&D Plan Revision: 2

Appendix C

Description of the Product

Executive Summary	The product is a portable/collapsible sling lift that allows for easy transportation of patients to and from multiple locations. Most sling lifts are made to take patients from one specific location to another specific location. For example, many lifts transfer patients from the bed to the wheelchair, yet they do not aid in transferring patients from the wheelchair to the car. Thus, the goal is to create a sling lift that can be utilized in numerous scenarios and easily collapsed for storage in homes, cars, etc. Furthermore, it will be cost effective, light, and safe for use to enable the enhancement of daily lifestyle activities.
Description of the Problem to be Solved	Sling, or Hoyer, lifts are often heavy and/or difficult to use/transport. Along with this, most are extremely expensive, limiting aid to the general population.
Needs Statement	A design for a cost effective, portable, light, automated, and easy-to-use lift that effectively lifts immobilized patients while prioritizing the safety of patients and caregivers.
Literature Review	Sling lifts are often used to transport patients from one place to another. In most cases, this movement takes place from bed to a wheelchair, but more recently, collapsible/portable sling lifts have become more popular as the demand for easy transport to and from doctor appointments and personal events has increased. While there are a few collapsible, portable hoyer lifts on the

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F01, Version B Design and Development Plan

Project Name: Collapsible Sling Lift	DHF # 2	D&D Plan Revision: 2

	market, many of them are very expensive. With the majority of the current options having a sticker price between fifteen hundred and ten thousand dollars, the high cost of these devices limit the accessibility to the general public. It was found that prioritizing a low price often leads to an increased risk of injury. Many operators have difficulties operating the lifts. This is due to either the presence of a complex protocol or inadequate training. It is also difficult for these caregivers to carry and transport the portable lifts into and out of their cars, houses, etc. While some of these lifts are portable, they are still quite heavy and a pain to carry around. Therefore, there is a need for a portable sling lift that is cost effective, safe for patients and caregivers, easy to operate, and light. *See attached*
Prior Art Search, Assessment, & Patentability	Description of existing patents: ● Patient Lift System ○ Ceiling mounted lift system with trolley and track. ● Hydraulic jack and patient lifting device ○ Hydraulic lift system with a manual handle to control the fluid reservoir for lifting and lowering patients. ● Lift System with Lowering Mechanism ○ Overhead rail mounted lift system with visual readout screen to display and transmit information to the operator.

	• Portable Transfer Chair and Lift
	  ○ "MegaMover" designed with waterproof webbing and additional handles that enables the patient to be moved in and out of a shower and toilet area.
	• Patient Support Lift Assembly
	  ○ Designed to raise and lower a patient to a desired height using a hoist and crank set up.
	• Sling Bar or Lift Strap Connector having an Integrated Scale with Tilt Compensation
	  ○ Integrated scale with the sling bar of the patient lift system to optimize lifting height.
	See attached

Competition & Differentiation	There are numerous sling lifts on the market that are considered portable, yet they lack the versatility to transport patients to and from all needed locations. This includes transitions from the bed to a wheelchair and the wheelchair to the car. These lifts are often extremely expensive, difficult to operate, and heavy, making them difficult to store and move. Our lift is designed to be lightweight, collapsible, safe, and cost effective for the general population. It also includes distinct features such as rechargeable battery packs, a square bar with a pin and socket system for enhanced safety, and a bag for easy transport of the collapsed parts.
Value Proposition & Differentiation	By creating a product that combines the functions of different lifts on the market, we are able to provide our customers with a

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F01, Version B Design and Development Plan

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	valuable alternative to purchasing multiple lifts for different applications.
Anticipated Regulatory Pathway	This is a Class II Device as stated by the FDA.
Reimbursement Strategy	The plan is to use cost-based reimbursement through insurance companies. These devices will be sold to members of the public as well as to nursing homes, hospitals, and similar care facilities.
Estimated Manufacturing Cost	$32.69 aluminum/lift, $12.24 steel/lift, $55/fabric sling, $133.90/sling cradle, $44/set of locking wheels locking wheels, $30/set of pins, $24/set of snap button locks, $63.03/lead screw, $189.05/motor, $29.95/carrying bag, $359.98/4 battery packs Manufacturing Machines/tools: Metal Laser Cutting Machine, Automated welding machine, drills
Potential Market & Global Impact	This product is intended for use in hospitals as well as the cars and homes of immobilized patients. This product specifically intends to increase mobility and affordability to allow immobilized patients to travel with more ease.
Intended Use / Indications for Use	The product is intended to be used to move patients from one seat to another seat. This includes transferring between beds, wheelchairs, and seats in homes, cars, medical clinics, etc. The product is intended to fold into a compact shape so that, through the use of a carrying bag, caregivers and medical personnel can easily carry and store the product. Furthermore, the use of

	wheels is intended to allow movement from one place to another while the patient is suspended in the sling.
Patient Population	The patient population will include teenagers and adults that are under 350 lbs and possess one or more disabilities that prevent them from being able to move from one seat to another without additional assistance.
Materials	By using aluminum 6061, the sling will be durable enough to support the weight of a human, and by making the aluminum rods hollow, it can remain light. Furthermore, we will use screws, hinges, fabric for the sling seat, locking wheels, a fabric bag for carrying the collapsed device, and rechargeable battery packs so that the device can be used in multiple locations.
Features	Specific features of the product include connection points, a pin and socket system, battery packs, wheels for transportation, a bag for transportation of the collapsed parts, a power screw system for lowering and lifting the patient, and hooks from which the sling will be hung.
Components	1. Pin and Socket 2. Power Screws/Motor 3. Rechargeable Battery packs 4. Top section 5. Bottom section 6. Base 7. Hooks for hanging sling 8. Bag and wheels for transportation

Add Rows as needed

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F01, Version B Design and Development Plan

Project Name: Collapsible Sling Lift	DHF # 2	D&D Plan Revision: 2

User Needs

Transfer User Need # and Design Input to QD0006F02, Design Summary Matrix.

If a user's need will not be fulfilled, provide a rationale for not fulfilling the need.

User Needs #	Description (User request)	Design Input or Rationale for Not Fulfilling Need
U1	Patient and Caregiver Safety	Pin and Socket, Power Screw system, and lightweight of the product
U2	Affordable Price	Buying one lift for multiple functions is cheaper than buying multiple lifts for separate functions
U3	Easy Operation	Battery packs, light material, button controlled electrical system
U4	Portability from Bed, Car, etc.	Square bar connected by pin and socket (compact folding), Bag for carrying
U5	Safe for transport	Light material, Supportive bag for carrying

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F01, Version B Design and Development Plan

Project Name: Collapsible Sling Lift	DHF # 2	D&D Plan Revision: 2

Part Number:

Part Number	**Description**	**UDI**[1]
#1	Attachment Bar with Hooks for Sling	Will be applied during manufacturing
#2	L shaped top horizontal bar	Will be applied during manufacturing
#3	Top half of vertical bar	Will be applied during manufacturing
#4	Lower half of vertical bar	Will be applied during manufacturing
#5	4 wheels	Will be applied during manufacturing
#6	2 legs of base	Will be applied during manufacturing

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F01, Version B Design and Development Plan

Project Name: Collapsible Sling Lift	DHF # 2	D&D Plan Revision: 2

#7	Horizontal beam of base	Will be applied during manufacturing
#8	Battery Packs/Charger	Will be included with the product
#9	Pin	Will be included with the product
#10	Socket for the pin	Will be applied during manufacturing

[1] Document UDI if UDI needs to be included on the CAD and/or etched on the physical part.

Add Rows as needed or attach Excel list.

Timeline

Attach a project timeline that defines at a minimum the project tasks, the name of the responsible team member, milestones, and the start date, and the due dates. The project timeline should be updated throughout the project and a copy of the current timeline should be reviewed during design review meetings. It is acceptable to use Excel, Project, or other project management tools.

See Appendix J

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F01, Version B Design and Development Plan

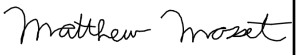
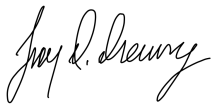
Project Name: Collapsible Sling Lift	DHF # 2	D&D Plan Revision: 2

Project Team

Function Required	**Name**
Product Development	Lydia Miller
Product Development	Lainey Hillman
Quality Assurance	Matthew Mosset
Regulatory Affairs	Macey Ross
Independent Reviewer	Troy Drewry
Additional Functions As Needed	
Manufacturing	Lainey Hillman
Sterilization	Macey Ross
Packaging	Macey Ross

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F01, Version B Design and Development Plan

Project Name: Collapsible Sling Lift	DHF # 2	D&D Plan Revision: 2

Approvals			
Title	Name	Signature	Date
Product Development	Lydia Miller		11/30/2023
Product Development	Lainey Hillman		11/30/2023
Quality Assurance	Matthew Mosset		11/30/2023
Regulatory Affairs	Macey Ross		11/30/2023
Independent Reviewer	Troy Drewry		11/30/2023

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F01, Version B Design and Development Plan

Project Name: Collapsible Sling Lift	DHF # 2	D&D Plan Revision: 2

Description of Design and Development Plan revisions.

Revision	Effective Date	Author	Description of Change
A	11/9/2023	Lainey, Lydia, Matthew, Macey	Initial Design and Development Plan
B	11/30/2023	Lainey, Lydia, Matthew, Macey	Revised Design and Development Plan

Revision History (Form)

Version	**CR number**	**Approval Date**
A	01	11/30/2023
B	02	12/8/2023

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F02, Version B Design Summary Matrix

Collapsible Sling Lift	DHF # 2	Matrix Revision: 2

Appendix D

User Need #[1]	Design Input[2]	Design Output[3]	Essential Req[4] (Yes/No)	Verification Activity[5]	Validation Activity[6]
U1	Complete Lift Product	*See CAD drawing*	Yes	Test Stability Balance and Weight Limit Test	Clinical Testing
U2	Affordable Price	*Target cost: 20% of sales price*	No	Build a product and determine the cost	If it is made in volume, determine the price drop
U3	Rechargeable Battery Packs, Power Screw system	*Power Requirements*	Yes	Mechanical Testing	Clinical Testing
U4A	90º angles at pin and socket point (compact folding).	*See CAD drawing* *Free Body Diagram* *Finite Element Analysis*	Yes	Mechanical Testing	Clinical Testing

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QD006F02, Version B Design Summary Matrix

Collapsible Sling Lift	DHF # 2	Matrix Revision: 2

U4B	Bag for Carrying	*See CAD drawing*	Yes	Weight Limit Test	Clinical Testing
U5	Safe for transport	*Light material*	Yes	Weigh Product	Clinical Testing

[1]Need # from QD006F01, Design and Development Plan
[2]Design Inputs are to be reviewed by team to ensure they are complete, not ambiguous, and do not conflict.
[3]Design outputs should include catalog numbers, drawings/specifications, material specifications, sterilization, packaging, labeling, features/components of the device, etc.
[4]Essential design requirements include those that if they are not met the product could cause harm to a patient or the device could malfunction. The essential design requirements are the features of the design that are deemed critical for function of the component. For these features, validation of the final parts should be performed or alternatively, 100% inspection of the essential design output requirement features may be performed.
[5] Verification activities could include mechanical testing, animal testing, review of drawings/specifications, tolerance stack-ups, labeling reviews, packaging, etc. List applicable document numbers and document names.
[6] Validation activities could include animal testing, clinical studies, saw bone labs, cadaver studies, visual inspection of product, etc. List applicable document numbers and document names.

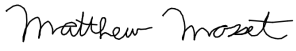
BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QP006F03, Version B Design Review 2

Collapsible Sling Lift	DHF # 2	DR1 Revision: 2

Appendix E

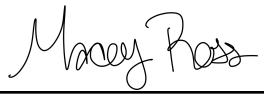
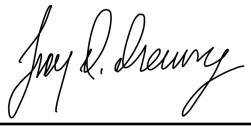
Design Review Meeting: Phase 1

User Needs

Review Date: 11/30/2023			
Attendees: Lainey Hillman, Lydia Miller, Matthew Mosset, Macey Ross, Troy Drewry			
Title	Printed Name	Signature	Date
Product Development	Lydia Miller		11/30/2023
Product Development	Lainey Hillman		11/30/2023
Quality Assurance	Matthew Mosset		11/30/203

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QP006F03, Version B Design Review 2

Collapsible Sling Lift	DHF # 2	DR1 Revision: 2

Regulatory Affairs	Macey Ross		11/30/2023
Independent Reviewer	Troy Drewry		11/30/2023

Add rows as needed

Meeting Review			
Items	Document Number	Document Revision	Comments
Design and Development Plan (Form # QD006F01)	#1	B	
Design Matrix Summary (Form # QD006F02)	#2	B	

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QP006F03, Version B Design Review 2

Collapsible Sling Lift	DHF # 2	DR1 Revision: 2

Add rows as needed

Proceed to Next Phase Decision
o Yes, Proceed to Phase 2: Design Requirements / Inputs. If applicable list any action items that will be included in Design Review Phase 2. Provide rationale as to why it is acceptable to proceed to next phase.
1. Add form edits as discussed in the meeting.
2. Implement rewording and other considerations as discussed.
o Not Approved to Proceed. Additional items required to be completed prior to moving to Phase 2. Provide list of action items, responsible person, and planned due date.
1.
2.
3.

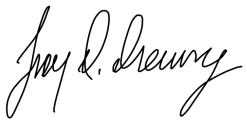
BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QP006F03, Version B Design Review 2

Collapsible Sling Lift	DHF # 2	DR1 Revision: 2

4.			
Approvals			
Title	Signature	Approval Decision	Date
Product Development	Lydia Miller	☑ Approve to move to Phase 2 ☐ Not Approved	11/30/2023
Product Development	Lainey Hillman	☑ Approve to move to Phase 2 ☐ Not Approved	11/30/2023
Quality Assurance	Matthew Mozet	☑ Approve to move to Phase 2 ☐ Not Approved	11/30/2023
Regulatory Affairs	Macey Ross	☑ Approve to move to Phase 2	11/30/2023

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QP006F03, Version B Design Review 2

Collapsible Sling Lift	DHF # 2	DR1 Revision: 2

		☐ Not Approved	
Independent Reviewer		☑ Approve to move to Phase 2 ☐ Not Approved	11/30/2023

Description of DR1 revisions.

Revision	Effective Date	Author	Description of Change
A	11/30/2023	Hillman, Miller, Mosset, Ross	Initial Draft
B	11/30/2023	Hillman, Miller, Mosset, Ross	Implementation of changes suggested by TD.

Add Rows as needed

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: Form**	QP006F03, Version B Design Review 2

Collapsible Sling Lift	DHF # 2	DR1 Revision: 2

Revision History (Form)

Version	CR number	Approval Date
A	01	11/30/2023
B	02	12/8/2023

Appendix F

Introduction

Purpose	This document defines the roles, phases, reviews, and design control and risk assessment process to be used by MLLM Innovations. This procedure details the activities necessary to complete a Design History File (DHF) for implants and any instruments that require design controls. Any functional interaction between the implant and appropriate instruments (i.e. mating parts, tolerance analyses) must be addressed in the implant DHF and further covered in the Design Validation, Risk Analysis, or other sections as appropriate.
Scope	The information in this document applies to MLLM Innovations in regards to regulatory-controlled implants and instruments manufactured or distributed by MLLM Innovations.

Roles/ Responsibilities

Function/ Role:	Responsibilities:
MLLM Innovations Lainey Hillman, Lydia Miller, Matthew Mosset, Macey Ross	¨ Trained and competent to the requirements of this procedure and their role on the team.
Project Manager Macey Ross	¨ Oversight of the overall project, and shall interpret the design specifications from the customer's perspective. ¨ Document Product Summary document, and shall evaluate the current market and determine the end user needs so that they may be translated to design inputs.

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: SOP**	QD006, Version A Design Control

Product Development Lydia Miller	¨ Designs the product, and establishes the inherent safety, effectiveness, and reliability of a device. ¨ Provides drawings and/or three-dimensional models. ¨ Maintains the design history file, as well as all documentation related to controlled changes to the design documents
Quality Assurance (QA) Matthew Mosset	¨ Overseeing the total quality system to ensure quality, safety, and effectiveness of a device in every significant area. ¨ Documenting Risk Assessment and Management Plan document.
Regulatory Affairs (RA) Macey Ross	¨ Determines regulatory path and product classification. ¨ Documents FDA submission documentation. ¨ Completes FDA Registration and Listing as needed. ¨ Completes FDA UDI registration as needed. ¨ Documents Europe submission documentation as applicable including CE Mark/Technical file, Essential Requirements Checklist (ERC), and Declaration of Conformity. ¨ Supports other international registration as applicable. ¨ Notifies global regulatory bodies, such as Notified Bodies, FDA, and/or Canada of changes as appropriate.

BIOMEDICAL ENGINEERING UNIVERSITY OF MISSISSIPPI **Document Type: SOP**	QD006, Version A Design Control

Manufacturing Coordination Lainey Hillman	¨ Liaison between the Design Team and the manufacturing site to ensure that Design Transfer is successfully completed including process risk assessment, process validation, and Device Master Record (DMR)/Medical Device File created. ¨ Works with the contract manufacturer to ensure all design control related documentation and process validations are completed and documented.
Independent Reviewer Troy Drewry	¨ Reviews product design and design control documentation as an independent reviewer with a fresh perspective. ¨ Provides objective assessment and sign-off of the project during Design Review meetings.

Process Detail

1. Design Development Plan

1.1. Product Develop documents the Design Development Plan on QD006F01 which details the user's needs, and the Design Summary Matrix on QD006F02 that relates user needs to design inputs and design outputs, and details the design verification and validation activities.

1.2. The QD006F01 Design Development Plan includes the following sections:

1.2.1. Description of the product including, but not limited to:

- **Executive Summary**

- **Description of the Problem to be Solved**
    - *See attached*
- **Needs Statement**
    - *See attached*
- **Literature Review**
    - *See attached*
- **Competition & Differentiation**
- **Value Proposition & Differentiation**
- **Prior Art Search, Assessment, & Patentability**
    - *See attached*
- **Anticipated Regulatory Pathway**
- **Reimbursement Strategy**
- **Estimated Manufacturing Cost**
- **Potential Market & Global Impact**
- **Intended Use / Indications for Use**
- **Patient Population**
- **Materials**
- **Features**
- **Components**

1.2.2. Members for the project team. At a minimum, this group must include members from Product Development, Quality Assurance, Regulatory Affairs, and an Independent Reviewer

1.2.3. The user needs from the customer. User needs that are not fulfilled should have a rationale provided to explain why the user need was not completed. The user needs should include the quality objectives and requirement for the product and they can be identified from many different sources, including customers, business development, product development, etc. These needs are the requirements for the final product that is translated into the production environment.

1.2.4. The need to establish processes, documents, and resources specific to the product including infrastructure and work environment.

1.2.5. Part number list of all device part numbers, along with a description of the device including sizing when applicable. It may be appropriate to include the product Universal Device Identifier (UDI) if the UDI needs to be included in the CAD or product specification.

1.2.6. QD006F01 Design Development Plan document is approved by the team indicating they agree with the plan and are the assigned to the project.

2. Design Inputs

2.1. Design Inputs are based on user needs, and are identified on QD006F02 Design Summary Matrix. Design Inputs are a set of user needs translated into tangible and verifiable terms that can be used to determine the Design Outputs. Design Inputs should be comprehensive and could include:

- Intended use / indications for use
- User / patient / clinical (interfaces or needs)
- Performance characteristics
- Safety requirements
- Installation and servicing requirements
- Safety and performance parameters (including standards)
- Biocompatibility and Toxicity
- Sterility
- Cleanliness
- Electromagnetic interference (EMI)
- Compatibility with accessories / auxiliary devices

- Compatibility with environment of intended use
- Human factors
- Clinical reports
- Physical / chemical characteristics
- Labeling and packaging
- Applicable regulatory requirements and standards
- Past design history files
- Applicable outputs of Risk Management
- Manufacturing capability

2.2. The project team must review the Design Inputs for ability to verify and validate and for incomplete, ambiguous, or conflicting requirements and resolve them prior to defining Design Outputs.

3. Design Outputs

3.1. Design Outputs should be identified for each Design Input, and documented on the QD006F02 Design Summary Matrix.

3.2. Design Outputs define and document Design Inputs in adequate and measurable terms. The Design Outputs should be complete and should include:

- Catalog numbers
- Drawings/specifications
- Materials specifications

- Monitoring criteria
- Measurement and inspection criteria
- Cleaning specification and procedures
- Sterilization specification procedures
- Packaging and shipping container specification and procedures
- Labeling content, specifications, and procedures
- Storage, handling, and distribution specifications including environmental requirements
- User training and training plan
- Handling, storage, distribution, and traceability specifications for the components and the final device
- Installation procedures including verification activities, as applicable
- Servicing procedures including verification activities, as applicable

3.3. Each Design Output should have an acceptance criteria defined that can be assessed during Design Verification.

3.4. All Design Outputs that are essential for the proper functioning of the device should be identified by the project team and noted on QD006F02. Design Summary Matrix Essential outputs include those that if they are not met the product could cause harm to a patient or the device could malfunction.

4. Design Verification

4.1. Design verification ensures that Design Outputs meet Design Input requirements.

4.2. Verification activities could include mechanical testing, animal testing, review of drawings, tolerance stack-ups, labeling reviews, packaging, etc.

4.3. Verification plans should be defined and include a method, acceptance criteria and as appropriate statistical techniques with a rationale for sample size. If the intended use of the medical device requires connection and/or interface with other medical device(s) the verification testing shall include testing the connected/interfaced devices.

4.4. Verification reports should be documented including the dates of testing, the results, conclusions, and identify the individuals responsible for the activities.

4.5. If testing is performed for verification, testing should be performed using production quality parts or their equivalents. If production quality parts are not utilized, a rationale should be provided to demonstrate the equivalency of the parts to production quality parts.

4.6. The Design Verification activities should be documented on QD006F02 Design Summary Matrix. All documents, including data and test reports, that include verification activities should be included in the DHF.

5. Design Validation

5.1. Design validation ensures that Design Outputs meet user need requirements.

5.2. Validation activities could include animal testing, clinical studies, saw bone labs, cadaver studies, visual inspection of product, etc.

5.2.1. A medical device used for clinical study is not considered to be released for use to the customer. Validation activities shall be completed prior to release for use of the device to the customer.

5.3. Validation plans should be defined and include methods, acceptance criteria and as appropriate statistical techniques with a rationale for sample size. If the intended use of the medical device requires connection and/or interface with other medical device(s) the validation testing shall include testing the connected/interfaced devices.

5.4. Cleaning, Sterilization and packaging validations need to be conducted and validation reports including methods, results and approvals need to be included in the DHF, when applicable.

5.4.1. Cleaning, packaging and sterilization validations are required for product provided sterile. Real time testing can be an open action item at product launch as long as accelerated testing is successfully completed.

5.4.2. Product shelf life, ship test, cleaning, and assembly validations should also be considered during this phase.

5.5. Validation reports should include the dates of testing, the results, conclusions, and identify the individuals responsible for the activities.

5.6. Validation activities should be done using production quality parts or their equivalents. A rationale for the choice of product used in validation should be documented. If production quality parts are not utilized, the rationale needs to demonstrate the equivalency of the parts to production quality parts.

5.7. The Design Validation activities should be documented on the QD006F02 Design Summary Matrix. All documents, including data and test reports, that include validation activities need to be included in the DHF.

6. Risk Assessment and Management Procedure

6.1. The Risk Management Plan and Report are documented on QD009F02. The process for assessment, scoring, and management of the project risks is documented in the FMEA QD009F01.

6.2. QD009F01 FMEA and QD009F02 Risk Management Plan and Report will be reviewed and updated periodically, per QD009 Risk Management.

7. Device Master Record (DMR)/Medical Device File & Device History Record (DHR)

7.1. The DMR/Medical Device File for each type of device shall include, or refer to the location of, the following information:

7.1.1. Device specifications (e.g., drawings, composition, formulation, component specifications, and software specification)

7.1.2. Routers and procedures/specifications for manufacturing, packaging, storage, handling, and distribution

7.1.3. Bill of Materials (BOMs)

7.1.4. Quality Inspection forms / documentation and procedure for measuring and monitoring

7.1.5. General description of the medical device, intended use/purpose, and labeling (including IFU(s), outer label and patient label, if applicable)

7.1.6. Installation and servicing specification, as applicable

7.2. The DHR must contain objective evidence of each type of documentation defined for the DMR/Medical Device File above.

8. Design Transfer Plan

8.1. QD006F06 Design Transfer Plan will be developed for each product to ensure outputs are verified as suitable for manufacturing before specifications are finalized and that production capability can meet product requirements. The plan will reference controlled records that are needed for the Device Master Record (DMR)/ Medical Device File.

8.2. MLLM Innovations will collaborate with vendors to establish a design transfer plan if product will not be manufactured in-house. Vendor's procedures can be utilized to ensure that the production, inspection, and packaging requirements are met.

8.3. QD006F06Design Transfer Plan will include the following information:

8.3.1. Scope of production components – Listing of components that will be produced as part of the product offering. This should be consistent with the part listing in the QD006F01 Design Development Plan, but may include subcomponent numbers.

8.3.2. Process list – A list of the processes used to produce the final components. For each process step, applicable specifications should be listed. Validation of each process step should be completed to ensure the process is well controlled. Alternatively, 100% inspection of the critical features of each component may be performed to ensure all components meet specifications.

8.3.3. Essential design outputs – The essential design outputs of the design should be identified. The essential design outputs are the features of the design that are deemed critical for function of the component. For these features, validation of the final parts should be performed or alternatively, 100% inspection of the essential design output features may be performed.

8.3.4. Component assembly methods – Lists the methods and work instructions that will be used for any assembly steps of the process.

8.3.5. Inspection methods – Lists the methods including gages and application work instructions that will be used to measure and inspect the device.

8.3.6. Labeling and packaging description – Description of the labeling that will be provided on or within the packaging. In some cases, an example label may be included in the document. Also describes the manner in which the product will be packaged.

8.3.7. Requirements for handling, storage, distribution, and traceability – Description of the infrastructure and environmental needs of the product during storage and distribution.

8.3.8. Risk management plan / report with design FMEA.

9. Design History File

9.1. The DHF is a compilation of documents that record the development history of an implant or instruments not considered Class I exempt and is required for all devices included in the scope of this procedure.

9.2. Approvals: Documents contained in the DHF that require approvals must show evidence of those approvals. The original deliverable and all subsequent revisions must be signed and dated by the required approvers. All revisions must be maintained within the DHF.

9.3. Changes to design control documents: Significant changes to documents will require a new revision. For minor changes, handwritten edits are acceptable with deletions crossed through and additions printed in pen (blue or black ink only). All handwritten changes must be initialed and dated in pen by the Project Team member making the change. Changes should follow QD010, Document and Change Control.

10. Phases

10.1. Phase 1 - User Needs: Concept phase which includes initiation of the project and project planning. The DHF is initiated in this phase. The initial user needs and design inputs should be defined. The initial risk assessment is initiated in this phase to identify all design inputs. Design Review 1 concludes this phase of the project and reviews the initial documents, such as the first revisions of the QD006F01 Design Development Plan, which includes the QD006F02 Design Summary Matrix.

10.2. Phase 2 - Design Development: The design outputs are determined and testing and activities associated with design verification are completed and reviewed. In some cases, design validation activities may be completed during this phase. The Project Team meets for Design Review 2 to review the testing associated with design verification and the current revision of the QD006F02 Design Summary Matrix. QD006F06 Design Transfer Plan is initiated once a more final design concept is developed. Regulatory filings may take place in the target markets once design verification is complete.

10.3. Phase 3 - Design Validation and Transfer: The activities associated with validation of the design are performed, and design transfer to the contract manufacturer is documented. The Project Team meets for Design Review 3 to review the design validation and the next revision of QD006F02 Design Summary Matrix. Actions items such as real time shelf life and packaging validations require years to complete. The product can be distributed with these actions open as long as the accelerated shelf life and packaging validations are complete. The product is released for distribution once Design Review 3 is complete and regulatory requirements are met.

11. Reviews

11.1. Design Review Process

11.1.1. Attendance: to initiate the Design Review meeting, a representative for each Project Team role must be in attendance. Additionally, an Independent Reviewer must be in attendance to provide objective assessment of the project. Attendance may be in the form of video or teleconference in cases where physical attendance is not possible. The name of each responsible party should be listed in the Design Review documentation.

11.1.2. Action items: At each Design Review, action items may be assigned to Project Team members if additional information or assessment is required. Action items may either be assigned to be completed prior to approval at the current Design Review step, or to be completed for presentation at the subsequent Design Review. If action items are required for approval at the current Design Review, a second Design Review meeting may be required to review the output from the action item.

11.1.3. Approval: Design Review approval is required before the Project Team may proceed to the subsequent phase of the project.

11.2. Design Review 1 (DR1):

11.2.1. Design Review 1 concludes the User Needs phase of the project, and approval initiates the Design Development phase.

11.2.2. Design Review 1 should assess documents associated with the Design and Development Planning.

11.2.2.1. QD006F01 Design and Development Plan.

11.2.2.2. QD006F02 Design Summary Matrix.

11.2.3. Meeting minutes, action items, and decision to move to next phase should be documented on QD006F03 Design Review 1.

11.2.4. The project team should sign off on QD006F03 Design Review 1 for attendance and decision to move to Phase 2.

11.3. Design Review 2 (DR2):

11.3.1. Design Review 2 concludes the Design Development phase of the project, and approval initiates the Design Validation and Transfer phase.

11.3.2. Design Review 2 should assess all documents associated with the Design Outputs and Verification.

11.3.2.1. The next revision of the QD006F01 Design and Development Plan.

11.3.2.2. The next revision of the QD006F02 Design Summary Matrix.

11.3.2.3. Testing associated with verification activities should also be reviewed.

11.3.3. Meeting minutes, action items, and decision to move to next phase should be documented on QD006F04 Design Review 2.

11.3.4. The project team should sign off on QD006F04 Design Review 2 for attendance and decision to move to Phase 3.

11.4. Design Review 3 (DR3):

11.4.1. Design Review 3 concludes the Design Validation and Transfer phase.

11.4.2. Design Review 3 should assess documents associated with the Design Validation and Transfer.

11.4.2.1. The next revision of the QD006F01 Design and Development Plan.

11.4.2.2. The next revision of the QD006F02 Design Summary Matrix.

11.4.2.3. Validation Testing should be reviewed.

11.4.2.4. The DMR/Medical Device File documentation should be reviewed.

11.4.2.5. Regulatory submission status should be reviewed.

11.4.3. Meeting minutes, action items, and decision to launch should be documented on QD006F05 Design Review 3.

11.4.3.1. Action items need to be completed and reviewed before product can be released for distribution. Actions items such as real time shelf life and packaging validations require years to complete. The product can be distributed with these actions open if the accelerated shelf life and packaging validations are successfully complete.

11.4.3.2. Distribution of product can occur once Phase 3 activities are complete and the regulatory requirements are met.

11.4.4. The project team should sign off on QD006F05 Design Review 3 for attendance and decision to launch.

11.5. Product Release:

11.5.1. Product can be released and placed into distribution once Phase 3 activities are complete and the regulatory requirements are met. The team will document launch decision on QD006F05 Design Review 3.

12. Document Control and Retention Procedures

12.1. Procedures related to initiation, review, and implementation of changes to revision-controlled documents is outlined in procedures QD010 Document and Change Control.

12.2. Any change to a product that has already completed phases of the design control process needs to be assessed for the impact to documents within the DHF.

12.2.1. The change impact to the function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use shall be documented.

12.2.2. The effect of the change on other components, parts, inputs, outputs, risk management, and other design control documents shall be documented.

12.2.3. The change shall be reviewed, verified, validated, and approved by the original approvers or functional areas.

12.3. Documents that need to be updated should be identified and updated appropriately.

12.3.1. Changes will be noted on the Revision History in the appropriate section on the appropriate form.

12.3.2. Handwritten changes or deletions should be crossed out, additions written in pen (blue or black only), and initialed and dated by the individual making the change.

12.3.3. When significant changes are made and a new revision of the record is created, the previous revision shall be maintained in the DHF.

12.4. New products being added to the family should also initiate a review of the documents within the DHF and updates should be made to the DHF documentation as needed.

12.5. Any document controlled in a different location, such as manufacturing documentation (e.g. drawings, labeling, DMR/Medical Device File), should be updated within that change control location. However, changes should be traced back to the DHF to determine if there are impacts to any other documents, such as the risk analysis or testing.

12.6. The Design History File (DHF) shall be maintained and include or reference storage locations of design documentation that demonstrates compliance to the requirements of this procedure.

References

- QPD006F01 Design and Development Plan
- QD006F02 Design Summary Matrix
- QD006F03 Design Review Phase DR1 Form
- QD006F04 Design Review Phase DR2 Form
- QD006F05 Design Review Phase DR3 Form
- QD006F06 Design Transfer Plan

- Ø QD009F02 Risk Management Plan and Report Form
- Ø QD009F01 FMEA Form
- Ø QD010 Document and Change Control
- Ø QD010F01 Change Request Form

Definitions

See QD007 Definition Glossary

Records

See QD010 Document and Change Control

Revision History

Version	CR number	Approval Date
A	01	11/30/23

Appendix G

Introduction

Purpose	This document defines the risk management process. This procedure defines risk management activities required, including criteria for risk acceptability.
Scope	The information in this document applies to products developed, manufactured, and/or sold by MLLM Innovations.

Roles/ Responsibilities

Function/ Role:	Responsibilities:
MLLM Innovations Project Team	· Implement and support Risk Management requirements
Project Manager	· Initiate QD009F02, Risk Management Plan and Report · Assure risk are identified, documented, and mitigated to an acceptable level · Obtain Executive Management approval for risk management activities · Maintain Risk Management File
Quality Assurance (QA)	· Establish and maintain Complaint Review · Trend product complaints, CAPAs, Non-Conforming Reports (NCR)
Regulatory Affairs (RA)	· Establish and Maintain Clinical Literature Review
Product Development	· Initiate and Maintain Risk Analysis (QD009F01, FMEA)
Executive Management	· Approve QD009F02, Risk Management Plan and Report · Approve product risk and residual risk · Approve risk/benefit analysis

Process Overview

Process Detail

1. Risk Management Plan and Report

1.1. The Project Manager begins the Risk Management Process by initiating QD009F02, Risk Management Plan and Report for a product.

1.2. The intended use of the product is documented in the Risk Management Plan.

1.3. Items included in the report will include, at least:

1.3.1.Complaint Review

1.3.2.Clinical literature Review

1.3.3.Risk Analysis

1.3.4.Trending related to product specific complaints, CAPAs, and/or Nonconforming Reports (NCR)

1.3.5.Rationale will be provided for any instance where the above is not provided.

2. Risk Analysis Identification of Hazards and Harms

2.1. Quality Assurance initiates the Risk Analysis process including initiating QD009F01, FMEA early in the design process to identify hazards as an input to User Needs and Design Inputs.

2.2. Identify and document hazards on QD009F01, FEMA.

2.2.1.Hazards should be considered from the perspective of the normal intended use of the device and the unintentional misuse.

2.2.2.A systematic analysis should be conducted considering the user, use environment, the device, and the patient. This analysis should assume no manufacturing defects and that the products are manufactured to specifications.

2.3. Tools that may help identify potential hazards include:

2.3.1.Draft instructions for use and/or instructions for use for similar product.

2.3.2.Review of past complaints for similar product.

2.3.3.A search of the FDA website for Medical Device Reporting MDR. (http://www.fda.gov/cdrh/maude.html): Manufacturers and User Facility Device Experience (MAUDE) Database. The online search allows queries for specific products, 510(k)s, and/or product codes.

2.3.4.A literature review using search engines such as MedLine (PubMed – http://www.ncbi.nih.gov/entrez/query.fcgi).

2.3.5.Interviews with users of the device including physicians, technicians, and nurses.

2.4. Each of the hazards can have multiple potential harms. Document the severity of each harm by assigning a severity rating. QD009F01, FMEA includes the following Severity Table:

Severity (SEV)		
Ranking	Definition	Effect
5	Catastrophic	Device failure or defect may cause death or permanent injury with or without warning of failure
4	Severe	Device failure or defect will cause severe injury which would necessitate revision surgery
3	Moderate	Failure renders device useless or will result in a minor injury of a non-permanent nature
2	Minor	Failure will result in no loss of product performance but may create some annoyance to user
1	None	No effect

2.5. Document the probability of occurrence of each harm. QD009F01 FMEA includes the following Occurrence Table:

Occurrence (OCC)		
Ranking	Definition	Frequency
5	Extremely High	Failure almost inevitable
4	High	Repeated failure
3	Likely	Occasional failure
2	Rare	Failure unlikely

1	Remote	Remote chance of failure

2.6. Calculate the Risk Index. Severity x Occurrence.

3. Risk Evaluation

3.1. Use Risk Index Table to evaluate risk level.

Risk Index Table							
			Hazard Severity Level (S)				
			None	Minor	Moderate	Severe	Catastrophic
			1	2	3	4	5
Occurrence	Extremely High	5	5	10	15	20	25
	High	4	4	8	12	16	20
	Likely	3	3	6	9	12	15
	Rare	2	2	4	6	8	10
	Remote	1	1	2	3	4	5

4. Risk Mitigation

4.1. If the risk can be eliminated, eliminate the risk. If the risk cannot be eliminated:

4.1.1.Reduce the risk to the extent possible,

4.1.2.Provide for protection appropriate to these risks, including the provisions of alarms, and

4.1.3.Provide, with the device, information relative to the risk that remain, and

4.1.4.Minimize the hazard from potential failures during the projected useful life of the device.

4.2. Risk mitigation to reduce risk to acceptable level may include:

4.2.1.Re-design of product

4.2.2.Design verifications and validations

4.2.3.Inspection of product

4.2.4.Labeling can warn about hazard but labeling alone does not mitigate the risk.

4.3. For risk that remain as a yellow or green level the remaining risk shall be addressed in the risk to benefit statement in the Risk Management Plan and Report Form QD009F02.

4.4. Additionally, for risk that remain as red the remaining risk shall be addressed in the risk to benefit statement and both Top Management and the Management Representative shall approve the QD009F01, FMEA and the QD009F02, Risk Management Plan and Report Form.

5. Evaluation of Overall Risk Acceptability

5.1. Evaluate risk of the product in its entirety and document the risk benefit summary including assessment of overall residual risk in QD009F02, Risk Management Plan and Report.

6. Risk Management Report

6.1. The Risk Management Report should be reviewed and approved by Executive Management.

6.2. The Risk Management Report should be approved before product release.

7. Production and Post Production Information

7.1. For post market surveillance, the QD009F02, Risk Management Plan and Report should be updated periodically (recommendation: at least annually for the first 3 years on the market and then every two to three years based on the performance and risk of the device).

7.2. Additional information that should be reviewed and included in the updates include CAPAs, complaints, customer feedback, audits, and non-conforming product.

References

- Ø QD009F01 FMEA
- Ø QD009F02 Risk Management Plan and Report
- Ø QD006 Design Control

Definitions

See QD007 Definition Glossary

Records/ Reports

See QD010 Document and Change Control

Revision History

Version	CR number	Approval Date
A	01	

Appendix H

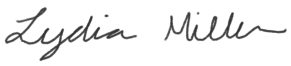
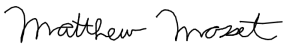
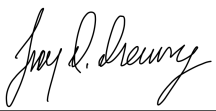
Project Name:

1. Purpose of Revision

Risk Management Plan (initial) Risk Management Report

Modification to Risk Management Plan Modification to Risk Management Report

2. Plan and Report Approvals

Revision	Team Member Function	Team Member Name (printed)	Team Member Approval Signature	Date
A	Product Development	Lydia Miller		2/29/2024
	Product Development	Lainey Hillman		2/29/2024
	Quality Assurance	Matthew Mosset		2/29/2024
	Regulatory Affairs	Macey Ross		2/29/2024
	Independent Reviewer	Troy Drewry		2/29/2024
	Other			

3. Risk Management Details

Risk Management Plan: This Risk Management Plan outlines Risk Management activities for the lifecycle of the products listed in Table 1-3 from the initial product development through post market surveillance. Post market surveillance will be performed as needed, but at a minimum an annual review is required for each product, as outlined in QD006, Design and Development.

Table 1: Part Number

Part Number	Description	
#1	Attachment Bar with Hooks for Sling	Will be applied during manufacturing
#2	L shaped top horizontal bar	Will be applied during manufacturing
#3	Top half of vertical bar	Will be applied during manufacturing
#4	Lower half of vertical bar	Will be applied during manufacturing
#5	4 wheels	Will be applied during manufacturing
#6	2 legs of base	Will be applied during manufacturing
#7	Horizontal beam of base	Will be applied during manufacturing
#8	Battery Charger	Will be included with the product
#9	Pin	Will be included with the product
#10	Socket for the pin	Will be applied during manufacturing

Add rows as needed or attach a list.

Table 2: Indications for Use

Indications for Use	
Foreseeable Misuse (In what way(s) might the medical device be deliberately misused?)	1. Engaging the collapsible feature of the lift while a patient is still in the swing. 2. Pushing someone back-and-forth on the swing. 3. Failure to secure and ensure device stability before use.

Table 3: Description of the Product

Risk Item	Description
Materials and / components	Battery packs, Aluminum metal, wheels, pin and socket, power screw system, hinges, screws, hooks
Energy delivered to and/or extracted	Rechargeable battery packs
Substances delivered to and / or extracted from the patient	N/A
Duration of Use	Around 5 minutes
What is the lifetime of the device?	Between 4 and 7 years, with inspections every 6 months
Biological materials processed by the device for subsequent re-use	N/A
Supplied sterile or intended to be sterilized by users	N/A

Intended to be routinely cleaned and disinfected by the user	N/A
Intended to modify the patient environment?	N/A
Measurements?	The device frame is 53.3 inches tall when fully lowered and 74.3 inches tall when fully extended. The base dimensions are 56.50 inches by 30 inches when the legs are square and 95.7 inches wide when legs are splayed
Is the device interpretative?	N/A
Intended for use in conjunction with medicines or other medical technologies?	Intended for use in conjunction with a chair sling
Unwanted outputs of energy or substances?	Dissipation of heat by batteries
Is the device susceptible to environmental factors?	The device is waterproof but should be used on stable ground
Essential consumables or accessories associated with the device?	N/A
Routine maintenance and/or calibration?	Yes, routine inspections every 6 months
Software?	N/A
Restricted “shelf life”?	N/A

Is the device subject to mechanical forces?	Yes, the device is intended to lift patients
Is the device intended for single use?	No, intended for multiple uses
Is safe disposal of the medical device necessary?	No
Is installation or special training required?	No
How will information for safe use be provided?	Instruction manual included
Can the user interface design features contribute to user error?	Yes, the user could collapse the device while in use or misuse the sling lift in another way.
Is the medical device used in an environment where distractions can cause use error?	Yes, the patient or other health care providers could serve as a distraction leading to misuse or user error.
Will new manufacturing processes be established or introduced?	No, we plan to use pre-existing manufacturing processes.
Is the device critically dependent on human factors such as user interface?	Yes, the device is operated by a care provider.
Does the device have connecting parts or accessories?	Yes, a sling chair is connected to the lift.

Does the device have a control interface?	Yes, controlled by buttons
Does the device display information?	No
Is the device controlled by a menu?	No
Will the medical device be used by persons with special needs?	Yes, it will be used to lift patients that have difficulty lifting themselves up and moving themselves.
Can the user interface be used to initiate user actions?	No
Does the medical device use an alarm system?	No
Does the medical device hold data critical to patient care?	No
Is the device intended to be mobile or portable?	Mobile and portable, as the device is collapsible
Does the user of the medical device depend on essential performance?	No

Add Rows as needed

3.1. For each risk area, mitigation activities actions are defined that are typically examined as part of risk management. For each action, the appropriate evidence consists of several different items. The evidence documents (physical copies or references) are placed in the Design History File and/or Risk Management File.

3.2. The following documents, at a minimum, should be included in the Risk Management File for each product:

3.2.1. Complaint Review

3.2.2. Clinical / Literature Review

3.2.3. Risk Analysis

3.2.4. Trending related to product complaints, CAPAs, Non-Conforming Reports (NCR)

4. Risk Management Report

4.1. At the completion of the project, this document becomes the cover sheet for the Risk Management Report. Documents are compiled and approved to verify that risk mitigation evidence is complete or a rationale has been written to justify why the activity was not necessary. Any key assumptions should be included in the objective evidence or rationale. Mark the items included in the report. For items not included a rationale to justify why the activity is not necessary must be attached.

☐ Complaint Review

☒ Clinical / Literature Review

☒ Risk Analysis

☐ Trending related to product specific complaints, CAPAs and/or NCRs

For items not included provide a rationale to justify why activity was not necessary:

Comments: ☐ n/a

5. Risk Acceptance Criteria

5.1. Risk acceptance is defined in QD006, Design and Development and QD009F01, FMEA and documented in the risk analysis.

6. Risk / Benefit Summary

6.1. Document an assessment of overall residual risk, if applicable.

6.2. Address the following questions:

6.2.1.Is the risk level acceptable? ☒ Yes ☐ No

6.2.2.Do the benefits outweigh the potential risk? ☒ Yes ☐ No

If the risk level is not acceptable, document how the benefits outweigh the potential risk.

Comments: ☐n/a

7. Post Market Surveillance

7.1. Post market surveillance will consist of periodic review and update, as needed, of applicable risk management documents, but at a minimum an annual review is required for each product, as outlined in QD006, Design and Development.

7.2. Specific post market surveillance activities will typically include complaint and adverse event analyses and review/update of appropriate risk analysis documents (i.e., FMEA).

8. Dates

8.1. Anticipated Launch Date: TBD

8.2. Next Risk Management Review (Month/Year): TBD

Revision History (Form)

Version	CR number	Approval Date
A	01	3/8/2024

Appendix I

Risk #	Feature / Function	Potential Failure Mode	Effects of Failure	SEV	Potential Causes	OCC
#	What is the feature/function under investigation?	In what ways does the key input go wrong?	What is the impact on the key output variables (customer requirements) or internal requirements?	How severe is the effect to the customer?	What causes the key feature/function to go wrong?	How often does cause or failure mode occur?
1	Device utilized in manner that is inconsistent with the intended use	Improper usage	Possible injury	4	Misuse of device	1
2	Backwards hinge	Support failure	Possible injury/device broken	4	exceeding weight capacity or misuse of device	3
3	Wheels	Failure to secure stop feature on the wheels	Possible injury to patient or device	3	misuse of device	1
4	Collapsible aspects	Collapsing during use	Possible injury to patient or device	4	misuse of device	1
5	Battery packs	Battery stops working during use	Halt of operation of the device	1	failure to replace or recharge battery after repetitive use	1
6	Material Failure	material fails due to improper use or wear	device fails to operate properly	4	failure to maintain regular inspection schedule and failure to use the equipement properly	1
7	Head clearance	Patient height over 6'5 does not provide efficient clearance	Patient's head is hit on bar if too tall.	2	Patient does not fall within the range of heights that are specified for this specific device	2
8	Part Failure (PF)					
8.1	PF1: Wheels	Wheels are not screwed in securely	Possible injury to patient or device	3	Manufacturing quality issues	1
8.2	PF2: Hooks	Hooks break during use	Possible injury to patient or device	4	Material failture/quality issues	1
9	Power Screw system failure					
9	Power Screw system failure 1:	Thread shearing	Device fails to operate properly, Possible injury to patient if thread shearing occurs	3	Failure to replace lift after lifetime as indicated in the instruction manual	3
9.2	Power Screw system faliure 2:	power screw rotates when motor is not powered	Device fails to operate properly, Possible injury to patient if occurs when patient is in the lifted position	3	Power is cut from motor	3
10	Carrying bag	wear of the bag could cause the straps to no longer be functional	Device could be damaged and harm could be caused to the caregiver or the person that is moving the collapsed device in the bag	2	Wearing of the straps or improper method of carrying the bag	2
11	Overturning of the device	Improper usage, swing back and forth in the sling	Possible injury/damage to the device	4	Missue of the device	1

Current Controls	Risk Index	Recommended Actions (if needed)	Responsible Person(s)	Actions Taken	SEV	OCC	Risk Index
What are the existing controls that prevent either the cause or the failure mode?	Severity x Occurrence	What are the actions for reducing the RPN. Should have actions only on high RPN's or easy fixes.	Who is responsible for the recommended action?	What actions have been taken and date completed?			
Instruction manual	4						
Instruction manual and warning labels along with routine device inspections every 6 months	15	Instead of backwards hinge, replace with pin and socket for horizontal top bar and vertical bar connection	CAD testing led to this change.	Has been implemented in design	4	1	4
Warning labels and instruction manual	3						
Warning labels and instruction manual	4						
Instruction manual	1						
Instruction manual and regular inspection schedule	1						
instruction manual and information packet	4						
Manufacturing quality control processes	3						
Manfacturing quality control processes	4						
Instruction manual, quality control	9						
	9			Worm and worm screw have been used to attach the power screw to the motor, preventing the power screw to be allowed to rotate unless the motor is rotating it.	3	1	3
Quality control and instruction manual	4						
Warning labels and instruction manual	4						

Appendix J

Date Completed	Event
9/27/23	Literature and Market Review Sheet Finished
10/16/23	Prior Art Search Finished
10/30/23	Research for Design
11/7/23	Design Controls Finished
11/30/23	Meeting with Independent Reviewer
12/8/23	Design and Development Sheet Finished
12/8/23	Design Summary Sheet Finished
12/8/23	Design Review Meeting #1
2/23/24	First CAD Model Completed
3/5/24	Decided to pivot to screw and rod lifting mechanism
3/8/24	Printed minature model of our frame
3/8/24	Gillespie Business Plan Competition Priority Registration Deadline
3/8/24	Honors College Draft Due
3/25/24	Design Review Meeting #2
3/28/24	Gillespie Business Plan Competition Final Registration Deadline
4/1/24	Submit to HOCO readers: Lainey, Macey, Lydia
4/12/24	Gillespie Business Plan Competition

Bibliography

Adaptive Specialties. “Handicare CARINA350 Portable Lift with Electric Base.” *Adaptive Specialties, Llc*, www.adaptivespecialties.com/handicare-carina350-portable-lift-with-electric-base.aspx. Accessed 09 Mar. 2024.

Anderson, Robin. “What Are Patient Sling Lifts.” *MobilePatientLift*, 18 Nov. 2022, www.mobilepatientlift.com/blogs/blog/what-are-patient-sling-lifts. Accessed 09 Mar. 2024.

Anderson, Robin. “The Dangers of Patient Lifts with Slings.” *MobilePatientLift*, 22 Dec. 2022, www.mobilepatientlift.com/blogs/blog/the-dangers-of-patient-lifts-with-slings. Accessed 14 Mar. 2024.

CDC. “Hip Fractures among Older Adults.” *Centers for Disease Control and Prevention*, 20 Sept. 2016, www.cdc.gov/falls/hip-fractures.html. Accessed 13 Mar. 2024.

Crail, Chauncey. “A Guide to the Best Hoyer Lifts.” Edited by Alena Hall, *Forbes*, Forbes Magazine, 17 Aug. 2023, www.forbes.com/health/medical-supplies/best-hoyer-lifts/. Accessed 13 Mar. 2024.

iHealthcareAnalyst, Inc. “Global Medical Lifting Slings Market $1.5 Billion by 2031.” *iHealthcareAnalyst, Inc. - Healthcare Market Research*, 22 Nov. 2023, www.ihealthcareanalyst.com/global-medical-lifting-slings-market/. Accessed 14 Mar. 2024.

Knickman, James R, and Snell, Emily K. “The 2030 Problem: Caring for Aging Baby Boomers.” *Health Services Research*, U.S. National Library of Medicine, Aug. 2002, www.ncbi.nlm.nih.gov/pmc/articles/PMC1464018/. Accessed 13 Mar. 2024.

Kucera KL;Schoenfisch AL;McIlvaine J;Becherer L;James T;Yeung YL;Avent S;Lipscomb HJ; “Factors Associated with Lift Equipment Use during Patient Lifts and Transfers by Hospital Nurses and Nursing Care Assistants: A Prospective Observational Cohort Study.” *International Journal of Nursing Studies*, U.S. National Library of Medicine, 3 Nov. 2018, pubmed.ncbi.nlm.nih.gov/30677588/. Accessed 13 Mar. 2024.

Marquis, Jeremiah. “6 Types of Hoyer Lift Slings and Their Features Explained.” *Mobility Plus Colorado*, 29 Dec. 2023, www.mobilitypluscolorado.com/blog/types-of-hoyer-lift-slings. Accessed 13 Mar. 2024.

MDS. “Medical Department Store.” *Electric Patient Lifts - Hoyer Lifts - Battery Patient Lifts*, Medical Department Store, www.medicaldepartmentstore.com/Electric-Patient-Lift-s/111.htm. Accessed 13 Mar. 2024.

Next Health. “AgileLife vs. Sling Lifts.” *AgileLife from Next Health, Inc.*, 28 Feb. 2019, www.agilelifemobility.com/agilelife-vs-sling-lifts#:~:text=Patient%20sling%20lifts%20(also%20called,lifting%20or%20lowering%20heavy%20loads. Accessed 09 Mar. 2024.

Renogy. “Everything You Need to Know about Lithium Battery Charging Cycles.” *Renogy Australia*, 19 July 2022,

au.renogy.com/blog/everything-you-need-to-know-about-lithium-battery-charging-cycles/. Accessed 29 Mar. 2024.

Tuffcare Store. “Amazon: Tuffcare Electric Patient Lift - Rhino Lift with Manual ...” *Amazon*, www.amazon.com/Tuffcare-Electric-Patient-Lift-Facilities/dp/B08BKHRVCQ. Accessed 28 Mar. 2024.

Worcest Store. “Engine Hoist.” *Amazon*, www.amazon.com/4000lbs-Folding-Hydraulic-Warehouses-Factory/dp/B0BG54R3L1. Accessed 28 Mar. 2024.