Mock 510(k)

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Indications for Use Statement (FDA Form 3881)

Device Name: Knee Rehabilitation Exoskeleton

Indications for Use Statement:

The Knee Rehabilitation Exoskeleton is indicated for prescription use in adult patients who have undergone total knee arthroplasty (TKA) and are undergoing rehabilitation to improve functional outcomes and quadriceps strength. This device is intended to aid in supervised physical therapy by providing controlled mechanical resistance and electrical stimulation to the quadriceps muscle. It is designed to support a structured progression through isometric, isotonic, and eccentric exercises, enhancing muscle recovery and mobility.

The device incorporates Neuromuscular Electrical Stimulation (NMES) to activate and strengthen the quadriceps muscle through targeted high-intensity electrical impulses, promoting muscle re-education and reducing muscle atrophy post-surgery. Additionally, Transcutaneous Electrical Nerve Stimulation (TENS) is included to provide pain relief during therapy sessions, enabling a more comfortable recovery experience.

The Knee Rehabilitation Exoskeleton is adjustable to fit a range of adult body sizes and is intended for stationary, indoor environments including hospitals, physical therapy clinics, and supervised at-home therapy settings. It is to be used under the direction and supervision of medical professionals who are trained in the device's setup, safety features, and therapy applications.

Prescription Use (Part 21 CFR 801 Subpart D): Yes

Intended Environment: Hospitals, physical therapy clinics, and supervised at-home therapy environments.

510(k) Summary or 510(k) Statement

1. **Submitter Information**

- **Submitter**: Florida State University
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- **Contact Person**: Joseph Liberato
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- **Submission Date**: 11/12/2024

2. Device Information

- **Device Name**: Knee Rehabilitation Exoskeleton
- **Classification Name**: Powered Exoskeleton for medical use, specifically for patient's post-total knee arthroplasty (TKA) rehabilitation
- **Product Code**: PHL
- **Regulation Number**: 21 CFR 890.3480
- **Device Class**: Class II

3. Predicate Device Information

- **Predicate Device Name 1**: HAL for Medical Use (Lower Limb Type)
  - **510(k) Number**: K171909
  - **Applicant**: Cyberdyne Inc.
- **Predicate Device Name 2**: Chattanooga Revolution Wireless
  - **510(k) Number**: K153696
  - **Applicant**: DJO, LLC

4. Device Description

The Knee Rehabilitation Exoskeleton is a rehabilitation device intended for adult patients who have undergone total knee arthroplasty (TKA). The device is designed to assist in post-operative recovery by combining mechanical resistance and electrical stimulation. It provides adjustable mechanical assistance to facilitate a progression of rehabilitation exercises—starting with isometric, moving to isotonic, and eventually incorporating eccentric exercises. These exercise modes specifically target quadriceps strength and functional recovery.

The device also features Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS) to assist with muscle activation and pain relief, respectively. The NMES mode is intended to reduce muscle atrophy by activating the quadriceps post-surgery, while TENS is designed to relieve pain, making the rehabilitation process more comfortable for patients. The device is adjustable to accommodate various patient sizes and is intended for use under supervision in hospitals, physical therapy clinics, or supervised at-home therapy environments.

5. Indications for Use

The Knee Rehabilitation Exoskeleton is indicated for prescription use in adult patients who have undergone total knee arthroplasty (TKA) and are undergoing rehabilitation to improve functional outcomes and quadriceps strength. It is intended for use in hospitals, physical therapy clinics, and supervised at-home therapy environments under the direction of trained medical professionals. The exoskeleton is not intended for sports or stair climbing. The exoskeleton training is intended to be used in conjunction with regular physiotherapy.

Before exercising, the Neuromuscular Electrical Stimulation feature can be used to help activate the quadricep muscle. The stimulation involves electric currents sent to skin surface electrodes.

6. Technological Characteristics and Substantial Equivalence

The Knee Rehabilitation Exoskeleton has similar technological characteristics to the HAL for Medical Use (Lower Limb Type) in terms of intended purpose and support for lower limb rehabilitation. Both devices include mechanical components to facilitate movement and resistance for strengthening muscles around the knee joint. The Knee Rehabilitation Exoskeleton is also like the Chattanooga Revolution Wireless in its use of electrical stimulation, providing muscle activation and pain relief options to complement mechanical assistance. The primary differences include customization of exercise for knee rehabilitation, adjustable resistance levels, and integrated data acquisition to track progress. These differences do not raise new safety or effectiveness questions.

7. Performance Testing

Performance testing includes:

- **Mechanical Testing**: Testing for range of motion and mechanical resistance to confirm device support for isometric, isotonic, and eccentric exercises specific to knee rehabilitation.
- **Electrical Testing**: Testing for NMES and TENS output parameters to verify the device operates safely within specified intensity ranges for therapeutic use.
- **Safety Testing**: Compliance testing with IEC 60601-1 (electrical safety) and IEC 60601-1-2 (electromagnetic compatibility) standards to ensure safe device operation in clinical settings.

8. Conclusion

The Knee Rehabilitation Exoskeleton is substantially equivalent to the identified predicate devices based on similar intended uses, patient population, and technological characteristics. This device offers a safe and effective option for supervised knee rehabilitation following TKA, combining mechanical assistance and electrical stimulation to improve patient outcomes in a clinical or supervised at-home environment.

Device Description

The Knee Rehabilitation Exoskeleton is a prescription medical device intended for adult patients who have undergone total knee arthroplasty (TKA) and require supervised physical therapy to improve quadriceps strength and functional mobility. The device combines mechanical assistance and electrical stimulation to support a structured rehabilitation program under the guidance of trained medical professionals.

Key Functionalities

1. **Mechanical Resistance**
    - The exoskeleton provides adjustable mechanical resistance to the knee joint to facilitate a progression of therapeutic exercises, including:
        - **Isometric Exercises**: Supporting static muscle engagement for initial strength building.
        - **Isotonic Exercises**: Enabling controlled movement to further develop muscle strength and endurance.
        - **Eccentric Exercises**: Assisting in gradual resistance training to increase strength as recovery progresses.
2. **Electrical Stimulation**
    - The device features two types of electrical stimulation modes to aid in muscle activation and pain management:
        - **Neuromuscular Electrical Stimulation (NMES)**: Delivers high-intensity electrical impulses to stimulate the quadriceps, promoting muscle activation and helping to reduce muscle atrophy following surgery.
        - **Transcutaneous Electrical Nerve Stimulation (TENS)**: Provides pain relief during therapy sessions, which enables patients to complete exercises with reduced discomfort.
    - Electrical stimulation is delivered through strategically placed electrodes on the skin, with parameters (e.g., intensity, frequency, and pulse width) adjustable based on the patient's needs and rehabilitation stage.
3. **Adjustable and Customizable Design**

   - The exoskeleton is designed with adjustable components to accommodate a range of body types and patient sizes, enhancing comfort and usability.
   - The device includes multiple modes to adjust mechanical resistance and electrical stimulation, allowing customization based on the patient's rehabilitation progress.
   - The electrical stimulation feature can be activated or deactivated, depending on patient-specific contraindications or preferences.
4. **Data Acquisition and Monitoring**
   - Integrated sensor modules within the device allow for real-time data acquisition during therapy sessions.
   - This data can be used to track patient progress, providing quantitative evidence of improvement, which may be valuable for both motivating patients and for documentation purposes in clinical and insurance settings.

Device Components

1. **Main Frame**:
   - The exoskeleton's frame is designed to be worn over the knee, extending from the thigh to the ankle. It is constructed with durable yet lightweight materials to provide stability without restricting natural movement.
2. **Mechanical Actuators**:
   - The mechanical actuators are responsible for providing the resistance needed for rehabilitation exercises. They are programmable to allow for varying levels of resistance to match the requirements of isometric, isotonic, and eccentric exercises.
3. **Electrodes and Electrical Stimulation Module**:
   - Electrodes are placed strategically on the patient's thigh to deliver NMES or TENS and are connected to an electrical stimulation module that controls intensity, frequency, and pulse duration. The module is designed with safety features to ensure stimulation within therapeutic limits.
4. **User Interface and Controls**:
   - A control interface allows medical professionals to adjust settings, monitor session progress, and switch between exercise modes and stimulation types. This interface is intuitive, ensuring easy operation by trained personnel.
5. **Power Source and Connectivity**:
   - The device is powered by an AC adapter compatible with standard 120V wall outlets in the United States. Battery backup may be available for short-term use if needed.

Safety Features

- **Mechanical Safety**: Mechanical stoppers and limited joint torque/velocity features are incorporated to prevent excessive joint movement, thereby reducing the risk of injury.

- **Electrical Safety**: The device complies with IEC 60601-1 standards for electrical safety and IEC 60601-1-2 standards for electromagnetic compatibility to ensure safe use in clinical environments.
- **Automatic Shut-off**: In the event of system faults or incorrect parameter settings, the device is programmed to shut off automatically to ensure patient safety.

Intended Use Environment

The Knee Rehabilitation Exoskeleton is intended for use in stationary, indoor settings, including hospitals, physical therapy clinics, and supervised at-home therapy environments. It is designed to be operated under the supervision of authorized medical personnel trained in its setup and application.

Executive Summary/Predicate Comparison

The Knee Rehabilitation Exoskeleton is a prescription medical device developed to assist adult patients who have undergone total knee arthroplasty (TKA) in their rehabilitation process. This device combines mechanical resistance and electrical stimulation to enhance muscle recovery and improve quadriceps strength. It is intended for supervised use in hospitals, physical therapy clinics, and home settings, supporting a structured progression through isometric, isotonic, and eccentric exercises.

Device Name	Device Classification Name	Product Code	510(k) Number	Applicant
HAL for Medical Use (Lower Limb Type)	Powered Exoskeleton	PHL - A powered exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened lower extremity limb(s) for medical purposes.	K171909	Cyberdyne Inc. 2-2-1 Gakuen-Minami Tsukuba, JP 305-0818
Chattanooga Revolution Wireless	Stimulator, Muscle, Powered	IPF – Powered muscle stimulator	K153696	DJO, LLC 1430 Decision Street Vista, CA

				92081

Device: Medical HAL Lower Limb Type

Characteristic	New Device	Predicate Device	Similar/Different
Body Coverage	Worn from thigh to ankle.	Worn over legs and around hips and lower torso.	Similar
Patient Height	150-190 cm	150-190 cm	Similar
Patient Weight	40-100 kg	40-100 kg	Similar
Intended Environment	· Flat surface of medical facilities and at home (indoor only).	· Flat surface of medical facilities (indoor only) · Must be used in combination with BWS systems.	Similar
Intended Users	Medical professionals	Medical professionals that have completed designated training program to use the device	Similar
Hardware and Main Components	· Main unit · Motor	The system consists of three major components: · Controller · Main unit · Sensor shoes	Similar
Device Lifetime	5 Years	5 Years	Similar
Range of Motion	· Knee: 120° flexion to 0° extension	· Hips: 120° flexion to -20° extension · Knee: 120° flexion to -6° extension	Similar
Safety Features	· Limited joint torque and joint velocity · Mechanical stoppers to prevent excessive joint flexion or extension.	· Limited joint torque and joint velocity · Mechanical stoppers to prevent excessive joint flexion or extension. · System fault for each component throughout operation · Task switching conditions that will not	Similar

		initiate incorrect task changes	

Device: Chattanooga Revolution Wireless

Characteristic	New Device	Predicate Device	Similar/Different
Prescription/OTC	Prescription	Prescription	Similar
Where Used	Physician office, physical therapy Clinic, Hospital, Nursing Home, Post Acute Care, Chiropractic Clinic	Physician office, physical therapy Clinic, Hospital, Nursing Home, Post Acute Care, Chiropractic Clinic	Similar
Target Population	Adult Population	Adult Population	Similar
Connection of device to electrodes		Stimulation Module is directly connected to the custom male SNAP assembled in the electrode. User Interface (LCD and buttons) is physically separated (Remote Control) and communicates wirelessly with up to four (4) stimulation modules. Stimulation safety remains fully managed by Stimulation Module electronic circuit itself.	
Number of Output Modes	Muscle stimulator: Electrodes	Muscle stimulator: Electrodes	Similar
Number of Output Channels	2	4	Similar
Software Control	Yes	Yes	Similar
Automatic Shut Off	Yes, On/Off Switch	Yes, On/Off Switch	Similar
Compliance with 21 CFR 898	Yes - 21CFR 898Performance standard for electrode lead wires and patient cables.	Yes - 21CFR 898Performance standard for electrode lead wires and patient cables.	Similar
Output Specifications (Waveform)			
Shape	Rectangular	Rectangular	Similar

Maximum Output Current (± 10%)	40mA – 100mA	120 mA @ 500 Ω 90 mA @ 2 kΩ 18 mA @ 10 kΩ	Similar

Substantial Equivalence Discussion

The Knee Rehabilitation Exoskeleton has been compared to two predicate devices to establish substantial equivalence: the HAL for Medical Use (Lower Limb Type) (K171909) and the Chattanooga Revolution Wireless (K153696). The following discussion outlines the substantial equivalence of the Knee Rehabilitation Exoskeleton to these predicate devices, focusing on intended use, technological characteristics, and safety features.

1. Intended Use and Patient Population

The intended use of the Knee Rehabilitation Exoskeleton aligns with both predicate devices:

- **Knee Rehabilitation Exoskeleton**: Intended for use in post-surgical rehabilitation of adult patients who have undergone total knee arthroplasty (TKA). The device assists in muscle recovery and strengthening through mechanical resistance and electrical stimulation in clinical or supervised settings.
- **HAL for Medical Use (Lower Limb Type)**: Intended for use as a powered exoskeleton for rehabilitation of lower extremity limb(s), operated by trained medical professionals in clinical settings.
- **Chattanooga Revolution Wireless**: Intended for muscle stimulation through electrical impulses to assist in muscle activation, commonly used for adult populations in clinical environments.

The substantial similarity in intended use—providing therapeutic support for muscle recovery and functional mobility—supports equivalence in terms of patient application and environment.

2. Technological Characteristics

The Knee Rehabilitation Exoskeleton combines both mechanical resistance and electrical stimulation, incorporating features from both predicate devices:

- **Mechanical Resistance**: Similar to the HAL for Medical Use, the Knee Rehabilitation Exoskeleton provides controlled mechanical assistance to facilitate isometric, isotonic, and eccentric exercises. Both devices include adjustable resistance and range-of-motion control to assist in muscle strengthening and functional recovery.
- **Electrical Stimulation**: Like the Chattanooga Revolution Wireless, the Knee Rehabilitation Exoskeleton uses electrical stimulation, including Neuromuscular Electrical Stimulation (NMES) for muscle activation and Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief. Both devices allow customization of output parameters such as intensity and frequency.

Although the Knee Rehabilitation Exoskeleton integrates both mechanical and electrical functionalities, these characteristics align closely with the predicate devices, which also serve to enhance muscle activity and support recovery in clinical environments. The combination of these features does not alter the intended therapeutic function or raise new safety concerns.

3. Safety and Risk Mitigation

The Knee Rehabilitation Exoskeleton incorporates similar safety features as the predicate devices to ensure safe use during rehabilitation:

- **Joint Protection**: Both the Knee Rehabilitation Exoskeleton and the HAL for Medical Use employ mechanical safeguards, including joint torque limits, velocity controls, and mechanical stoppers, to prevent excessive joint movement and reduce the risk of injury.
- **Automatic Shutoff**: Both the Chattanooga Revolution Wireless and the Knee Rehabilitation Exoskeleton include an automatic shutoff feature, which activates in case of system faults or incorrect parameter settings, ensuring patient safety.
- **Compliance with 21 CFR 898 and IEC Standards**: The Knee Rehabilitation Exoskeleton complies with 21 CFR 898 requirements for electrode lead safety and meets IEC 60601-1 and IEC 60601-1-2 standards for electrical safety and electromagnetic compatibility. This is consistent with the safety measures and compliance standards observed in the predicate devices.

4. Differences and Justification

While the Knee Rehabilitation Exoskeleton integrates both mechanical and electrical components, this difference does not introduce new risks:

- **Combined Functionalities**: The device's combination of mechanical resistance and electrical stimulation allows it to provide a more holistic rehabilitation approach by targeting both muscle strengthening and pain management. This integration is justified as it aligns with the device's therapeutic goals and does not introduce risks beyond those already addressed by the individual functionalities of the predicate devices.
- **Data Acquisition and Progress Tracking**: The Knee Rehabilitation Exoskeleton includes a data acquisition feature to monitor patient progress, which is not present in the predicate devices. This feature is designed to enhance patient motivation and provide clinical documentation but does not impact the device's safety or effectiveness.

Conclusion

The Knee Rehabilitation Exoskeleton is substantially equivalent to the HAL for Medical Use and Chattanooga Revolution Wireless in terms of intended use, technological characteristics, and safety measures. Any differences, such as the integration of mechanical resistance and electrical stimulation or the addition of data tracking, are minor and do not raise new questions of safety or effectiveness. These elements collectively demonstrate that the Knee Rehabilitation Exoskeleton is as safe and effective as the predicate devices for post-TKA rehabilitation.

Proposed Labeling

1. Device Label

- **Device Name**: Knee Rehabilitation Exoskeleton
- **Intended Use**: Prescription device for use in rehabilitation following total knee arthroplasty (TKA) to aid in quadriceps strengthening and functional mobility improvement.
- **Manufacturer**: Arce's Exoskeleton Group
- **Product Code**: PHL

2. Instructions for Use

- **Indications for Use**: The Knee Rehabilitation Exoskeleton is intended for prescription use by trained medical personnel in clinical or supervised home settings to support TKA rehabilitation through mechanical resistance and electrical stimulation.

Preparation and Setup:

- Ensure the device is placed on a stable, dry surface.
- Connect to a standard 120V battery power.
- Fit the device securely on the patient, adjusting straps to ensure comfort around the thigh, knee, and ankle.

Operation:

- **Mechanical Resistance**: Select the appropriate exercise type (isometric, isotonic, eccentric) based on the rehabilitation stage, adjusting resistance settings as needed.
- **Electrical Stimulation**: Place electrodes on the quadriceps, choosing either NMES for muscle activation or TENS for pain relief, and adjust intensity and frequency according to therapeutic goals.
- **Data Acquisition**: Enable real-time data tracking to document progress.

Post-use and Shutdown:

- Power off the device, disconnect, and carefully remove from the patient.
- Sanitize electrode contact points as per manufacturer instructions.

3. Patient Labeling

- **Device Purpose**: The Knee Rehabilitation Exoskeleton is designed to assist in recovery following knee replacement surgery, helping to build strength and manage pain.
- **Patient Instructions**:
    - Use the device only under supervision by medical professionals.

    - Report any discomfort or pain during use to the attending therapist.
    - Refrain from operating the device independently.
- **Safety Information**:
    - Avoid contact with water while using the device.
    - If you have any implanted electronic devices, inform your therapist before using the device.

Sterilization and Shelf Life

The **Knee Rehabilitation Exoskeleton** is not intended to be provided as a sterile device. However, certain components, including electrodes and skin-contact surfaces, require proper cleaning and disinfection between uses to ensure patient safety and device longevity.

1. Cleaning and Disinfection Guidelines

- **Reusable Components**: The electrodes (some types), straps, and other skin-contact parts of the Knee Rehabilitation Exoskeleton are designed for repeated use. Users are advised to clean and disinfect these parts per manufacturer instructions after each session.
- **Disinfection Procedure**: Approved hospital-grade disinfectants should be used to sanitize the device's skin-contact areas to prevent contamination and maintain patient safety. The device's materials have been tested to ensure compatibility with standard disinfecting agents.

2. Shelf Life and Device Longevity

- **Expected Shelf Life**: The Knee Rehabilitation Exoskeleton has an estimated shelf life of 5 years, based on mechanical durability and testing of key components such as actuators, electrodes, and connectors.
- **Shelf-Life Validation**: To confirm the device's shelf life, the following tests were conducted:
    - **Mechanical Testing**: Repeated load and resistance tests on actuators and mechanical joints to simulate daily use over five years.
    - **Material and Component Integrity Testing**: Evaluations of materials (e.g., plastics, straps, and electrode connectors) to confirm long-term durability under normal operating conditions.

3. Packaging Validation

- **Protective Packaging**: The device packaging is designed to protect the device components during shipping and storage. Packaging integrity tests have been performed

to ensure that the device remains undamaged and ready for use during the expected storage period.

Biocompatibility

The Knee Rehabilitation Exoskeleton contains components that directly contact patient skin, specifically in areas around the thigh, knee, and ankle. These contact points involve materials such as electrodes and adjustable straps that are designed to remain in contact with the skin for the duration of rehabilitation sessions. To ensure safety, all materials used in skin-contacting components have been assessed for biocompatibility in accordance with ISO 10993-1 standards for biological evaluation of medical devices within a risk management framework.

The primary materials that contact the skin include soft medical-grade silicone for electrodes and synthetic fabrics for straps. These materials have been chosen based on their compatibility with skin contact and history of safe use in medical applications.

Biocompatibility Testing

Test	Purpose	Results
Cytotoxicity	Evaluates if materials cause toxic reactions at a cellular level.	No toxic reactions observed in direct or indirect contact with skin.
Sensitization	Assesses potential to cause allergic reactions, such as dermatitis.	No allergic reactions reported, ensuring safe, prolonged use.
Irritation	Confirms that materials do not provoke skin irritation, redness, or inflammation with repeated contact.	No irritation detected, confirming suitability for repeated patient use.

All components adhere to a documented risk management plan to mitigate any risks associated with skin contact. The plan includes pre-market testing and post-market surveillance to ensure continued safety.

To prevent skin irritation or contamination, the device's skin-contacting components are designed for repeated cleaning and disinfection according to hospital-grade procedures. Materials have been validated to withstand regular disinfection without degradation of biocompatibility or functionality.

Software

The software integrated into the knee rehabilitation exoskeleton is essential for managing device functionality, including user interface controls, exercise modes, and real-time data acquisition. The software documentation has been developed in compliance with FDA recommendations for medical devices, tailored to the specific requirements of this device.

Level of Concern:

Based on the FDA's guidelines, the software for the knee rehabilitation exoskeleton is classified as having a **moderate level of concern**. This classification is due to the software's role in controlling therapeutic features (e.g., electrical stimulation intensity and duration) that could affect patient safety if malfunctions occur.

Software Documentation Provided:

1. **Software Requirements Specification (SRS)**: Defines the functional and performance requirements of the software, including control over exercise modes, electrical stimulation settings, and data monitoring.
2. **Software Design Specification (SDS)**: Details the software architecture, flow, and control mechanisms to ensure reliable functionality across different rehabilitation stages.
3. **Hazard Analysis**: Identifies potential hazards associated with software use, with specific focus on patient safety. Risk mitigation strategies are included to address scenarios such as incorrect stimulation parameters.
4. **Verification and Validation Testing**: Comprehensive testing has been conducted to verify software functionality and ensure that all requirements meet specified criteria. This includes testing under various scenarios to confirm reliable performance in clinical and supervised home settings.

Cybersecurity Considerations:
The Knee Rehabilitation Exoskeleton software is equipped with cybersecurity measures to protect against unauthorized access and potential data breaches. Key cybersecurity features include:

a. **Access Control**: Only authorized medical personnel can modify device settings, ensuring patient data and safety are protected.
b. **Data Encryption**: Sensitive patient data recorded by the device, such as progress tracking metrics, is encrypted to protect patient confidentiality.

c. **Firmware Update Protocol**: The device includes secure firmware update capabilities, allowing safe and timely updates to address potential security vulnerabilities or software improvements.

These measures collectively ensure that the software for the Knee Rehabilitation Exoskeleton meets FDA requirements for moderate-level medical devices, providing safe, reliable, and secure functionality in clinical and home rehabilitation environments.

Electromagnetic Compatibility and Electrical Safety

The Knee Rehabilitation Exoskeleton system is a Class II medical device that has been tested and verified for compliance with the following applicable standards for electromagnetic compatibility and electrical safety:

- **IEC 60601-1:2005 + A1:2012** - *Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.* This standard ensures the device meets essential safety requirements, minimizing risks associated with electrical hazards.
- **IEC 60601-1-2:2014** - *Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.* This standard confirms that the device operates safely in environments with potential electromagnetic interference without affecting other electronic equipment.
- **IEC 60601-1-11:2015** - *Medical Electrical Equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home health care environment.* This standard verifies the device's safety and usability in a home setting.
- **IEC 60601-2-33:2019** - *Medical Electrical Equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.* Ensures the device's safety near common magnetic resonance imaging equipment found in rehabilitation facilities.
- **ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012** - *Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1, MOD).* This U.S.-specific adaptation aligns with general safety performance requirements and is critical for electrical safety compliance in the U.S. market.

Test Objective	Pass/Fail Criteria	Test Results
Verify that device meets **IEC 60601-1:2005 + A1:2012** requirements (General electrical safety)	See **Exhibit A**. IEC 60601-1 TEST REPORT for Pass/Fail criteria	Pass
Verify that device meets **IEC 60601-1-2:2014** requirements (EMC emissions and immunity)	See **Exhibit B**. IEC 60601-1-2 TEST REPORT for Pass/Fail criteria	Pass

Verify that device meets **IEC 60601-1-11:2015** standard (Home healthcare environment safety)	See **Exhibit C**. IEC 60601-1-11 TEST REPORT for Pass/Fail criteria	Pass
Verify that device meets **IEC 60601-2-33:2019** standard (Safety near MRI equipment)	See **Exhibit D**. IEC 60601-2-33 TEST REPORT for Pass/Fail criteria	Pass
Verify that device meets **ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012** (U.S. electrical safety requirements)	See **Exhibit E**. ANSI/AAMI ES60601-1 TEST REPORT for Pass/Fail criteria	Pass

The Knee Rehabilitation Exoskeleton has met all testing requirements under these standards, confirming that it is safe for both clinical and supervised home use, providing reliable operation free from electromagnetic interference and electrical hazards.

Performance Testing – Bench

For the Knee Rehabilitation Exoskeleton, bench testing is our main approach since it's the easiest and most cost-effective way to check that the device works as intended. This type of testing lets us evaluate things like resistance, range of motion, and the electrical stimulation settings in a controlled setup. We might also do some biocompatibility tests in a wet lab, which involves testing with cells *in vitro* to ensure that any materials in contact with the body are safe. Cadaver testing could be an option too, as it allows us to see how the device performs on human anatomy, though this would be more for larger-scale projects. Overall, bench testing provides a strong foundation for proving that our device functions safely and as designed. [3]

Performance Testing - Animal

Although animal testing isn't part of our senior design project, it's a common next step in device development for products that interact with living tissues. For the Knee Rehabilitation Exoskeleton, however, animal testing is less applicable since it's specifically designed for human anatomy and physiology. In cases where animal testing would be considered, it's essential to evaluate the pros and cons of using small versus large animal models.

- **Small Animals** (e.g., rats, mice) are often more accessible and less costly for initial biological testing. They're useful for understanding basic physiological responses and provide preliminary data on biocompatibility or immune responses. However, small animals may not accurately replicate human joint mechanics, muscle structures, or the forces involved in human-sized rehabilitation, which limits their effectiveness in testing devices like an exoskeleton.
- **Large Animals** (e.g., sheep, pigs) offer a closer approximation to human anatomy and biomechanics, which can be beneficial for mechanical and physiological evaluations. Large animals provide better models for understanding how the device would function in a size and structure closer to that of humans, especially for weight-bearing and joint movement. However, these tests are typically more expensive, require specialized facilities, and involve more stringent ethical considerations and regulatory oversight.

If animal testing was required, this would be overseen by the Institutional Animal Care and Use Committee (IACUC) to ensure all ethical guidelines are followed. [4]

Performance Testing - Clinical

Clinical testing is a critical phase for verifying that the Knee Rehabilitation Exoskeleton is safe and effective for actual patient use. To begin clinical trials, approval from an Institutional Review Board (IRB) is required to ensure that the study is ethical and that participants are protected. In some cases, an **Investigational Device Exemption (IDE)** from the FDA may also be necessary. [5]

An IDE allows a device that hasn't yet received full FDA approval to be used in clinical studies for data collection on its safety and effectiveness. It's typically applicable in situations where there's significant potential for a new device to benefit patients, but comprehensive data is needed before full market approval. IDEs are especially relevant for devices targeting rare diseases, where few treatment options are available, or for breakthrough technologies with unique therapeutic potential. Under an IDE, researchers can gather essential data to demonstrate that the device performs safely and effectively, which is essential for FDA consideration.

During clinical testing, the most robust evidence comes from randomized controlled trials, which minimize bias and provide strong, reliable data. Alongside clinical data, we'd also gather economic information to support reimbursement claims, demonstrating that the device is not only effective but also cost-beneficial. Intellectual property considerations and market feasibility also play a role in clinical testing, ensuring that our device can succeed both clinically and commercially if it reaches broader use.

Note:

Overall, in a real-world setting we would need to prove that our device is safe and effective for the FDA, but we should do so in the least time-consuming, cheapest way (maintaining safety standards).

To avoid going through clinical trials, we can do the following:

- Pay $75,000 to some lobbyists so they can advocate for changes in the law.
- Wine and dine the senators in charge of those laws.
- Wait until a similar idea comes out so they can do all the clinical trials, and we just put them as a predicate device.

References

[1] CYBERDYNE Inc. **510(k) Summary: HAL for Medical Use (Lower Limb Type)**. 510(k) No. K171909. U.S. Food and Drug Administration, December 15, 2017. Available from CYBERDYNE Inc., Tsukuba, Japan. Retrieved from the FDA's public database.

[2] DJO, LLC. **510(k) Summary: Chattanooga Revolution Wireless**. 510(k) No. K153696. U.S. Food and Drug Administration, April 11, 2016. Available from DJO, LLC, Vista, California. Retrieved from the FDA's public database.

[3] American Society for Testing and Materials (ASTM). **ASTM F2944-12(2020): Standard Guide for Presentation of Bench and Animal Testing Results for Spinal Implant Constructs in a Standardized Format**. ASTM International, 2020.

[4] Institute for Laboratory Animal Research. **Guide for the Care and Use of Laboratory Animals**. 8th Edition. National Academies Press, 2011.

[5] U.S. Food and Drug Administration (FDA). **Design Considerations for Pivotal Clinical Investigations for Medical Devices; Guidance for Industry, Clinical Investigators, Institutional Review Boards and FDA Staff**. November 7, 2013.