510(k) Summary
as required by 21 CFR 807.92
K183152

1 Submission Information

1.1 Device Name

Phoenix™

1.2 Submission Sponsor

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1.4 Submission Preparation Date

K183152 – 15 April 2019

2 Device Identification

Trade Name: Phoenix™
Common Name: Powered Exoskeleton
Manufacturer: US Bionics, Inc. (DBA suitX)
Classification Name: Powered Exoskeleton
Device Classification: Class II, 21 CFR 890.3480
Product Code: PHL

3 Legally Marketed Predicate Device

Trade Name: Indego®
Manufacturer: Parker Hannifin Corporation (Parker Hannifin)
Classification Name: Powered Exoskeleton
510k Number: K152416
Submission Date: 2/26/2016

4 Device Description

The Phoenix™ is a wearable, powered exoskeleton that assists a trained user to sit, stand, walk, and turn. The Phoenix consists of a pair of motorized leg braces coupled to a torso module, a lithium-ion battery pack, a main controller unit, and a wireless user interface attached to the handle of an assistive device (such as a crutch, walker, or parallel bars), control software, and mobile Android tablet hosting a mobile app. The Phoenix dimensions, such as spine length, torso hip width, femur length, femur bracket, tibia length, tibia bracket, and foot plate length can be adjusted individually. The Phoenix is coupled to the user via soft-good components (i.e. shoulder straps, waist pads, thigh straps, and shin pads), which can be adjusted to accommodate various users' dimensions.

5 Indication for Use

The Phoenix orthotically fits to the lower limbs and trunk. The device is intended to enable individuals with spinal cord injury at levels T4 to L5 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. This device is not intended for sports or stair climbing.

6 Training

Training is a critical and required component of using the Phoenix™ exoskeleton. Patients and Clinicians must undergo training developed by suitX to learn proper use of the Phoenix device. The four-phase training program described in this guide is designed for training clinicians on the proper use and fit of the Phoenix. Refer to Table 1 below for the training sequence.

Table 1 Clinical Certification Training 4 Phase Training Program

①	②

• Device Overview
• Demonstration of ExoControl App Use
• Patient Measurement
  ○ Tibia Length
  ○ Femur Length
  ○ Torso Width
  ○ Torso Height
• Adjustment of Phoenix to fit Patient
  ○ Leg Adjustment
  ○ Torso Adjustment (Width and Height)
  ○ Footplate Adjustment
• Safeguard Patient during maneuvers
  ○ Standing Up
  ○ Walking
  ○ Turning
  ○ Sitting down
• Documentation of settings, measurements, and outcomes (patient's maneuvers).
	• Review of phase 1 training
	• Session preparation and procedure
	• Practice donning the device
	• Practice resting while standing
	• Review of fail-safe sitting procedure
	• Review of what to do in case of fall
	• Demonstrate storage of device
	• Review troubleshooting of device

③	**④**
• Practice setting up and conducting an entire test session • Review of phase 1 and 2 training	• Review of any outstanding questions from phase 1-3 • Certification

7 Substantial Equivalence (SE) Discussion

The following table compares the Phoenix™ to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The technological similarities between the subject device and the predicate device are substantially equivalent. The subject device does not raise any new issues of safety or effectiveness. **Table 1**, below, provides a summary comparison of the technological characteristics.

Table 1. Technological SE Comparison between Phoenix and Predicate

Manufacturer	**SuitX**	**Parker Hannifin**	**Significant Differences**
Trade Name	**Phoenix Medical Exoskeleton**	**Indego®**	
510(k) Number	K183152	K152416	N/A
Product Code	PHL	PHL	Same
Regulation Number	890.3480	890.3480	Same
Regulation Name	Powered Exoskeleton	Powered Exoskeleton	Same
Indications for Use	The Phoenix Medical Exoskeleton orthotically fits to the lower limbs and the trunk; the device is intended to enable individuals with spinal cord injury at levels T4 to L5 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. This device is not intended for sports or stair climbing.	The Indego® orthotically fits to the lower limbs and the trunk; the device is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The Indego is not intended for sports or stair climbing.	Similar; the Phoenix indications for use are the same as the predicate device when used in rehabilitation institutions.

Manufacturer	SuitX	Parker Hannifin	Significant Differences
Trade Name	**Phoenix Medical Exoskeleton**	**Indego®**	
Body Coverage	Worn over legs and around hips and lower torso; shoulder straps for additional stability	Worn over legs and around hips and lower torso	Similar; the components are worn around the legs and torso with the control unit of the device integrated into the hip segment. A rigid back is connected to the hip segment and worn in a similar fashion as a backpack. The rigid back of the torso module of the Phoenix is similar to other FDA cleared exoskeletons including the EKSO (K161443) and REWALK (K160987). No additional safety or efficacy concern as the component configuration is similar for the legs, hip, and torso of the patient.
Size of Components	Modular Adjustable Medium, and Large upper leg, lower leg; and adjustable torso components; control unit integrated in torso unit	Modular Small, Medium, and Large upper leg, lower leg, and hip components; control unit integrated in hip unit	Similar; adjustability provided by manually adjusting the length of hard components. Control unit is integrated in hip unit. No additional safety or efficacy concern as the component configuration is similar for the legs, hip, and torso of the patient.
Mobility Aid	Crutches or walkers	Crutches or walkers	Same
Ability of User Mobility	Sit, stand, walk, and turn	Sit, stand, walk, and turn	Same
Walking Speed	~ 2 km/hr.	~ 2 km/hr.	Same
Grade Inclination	5 degrees	5 degrees	Same

Manufacturer	SuitX	Parker Hannifin	Significant Differences
Trade Name	**Phoenix Medical Exoskeleton**	**Indego®**	
Type of Surface	Smooth, cement, carpet	Smooth, grass, cement, carpet, transitions, thresholds	Similar; the Phoenix surface types are the same as the predicate device when used in rehabilitation institutions.
Patient Population	Adults over age of 18 with Spinal Cord Injury (SCI) from T4 to L5	Adults over age of 18 with Spinal Cord Injury (SCI) from T4 to L5	Same
Height of Patient	61” to 75” (1.55 to 1.91m)	61” to 75” (1.55 to 1.91m)	Same
Weight of Patient	Up to 200 lbs. (90.7 kg)	Up to 250 lbs. (113 kg)	Similar; the device accommodates lighter weight patients and does not present any additional safety or efficacy concerns.
Control Method	Remote control on the walker or crutch to trigger all transitions	Uses postural cues to trigger all transitions	Similar; the remote control provides the trained user direct control over the device operation. Additionally, the remote control is used to trigger sit-to-stand and stand-to-sit. No additional safety or efficacy concerns have been identified.
Range of Motion	**Hip:** 140° flexion to 38° extension **Knees:** 110° flexion to 5° extension	**Hip:** 110° flexion to 30° extension **Knees**: 110° flexion to 10° extension	Similar; there is a larger range of motion for the Phoenix device to allow easier sit-to-stand transitions. No additional safety or efficacy concerns as clinical data supports the safe use of the device for ambulation and sitting/standing transitions.

Manufacturer	SuitX	Parker Hannifin	Significant Differences
Trade Name	**Phoenix Medical Exoskeleton**	**Indego®**	
Weight	33 lbs. (15kg)	26 lbs. (12kg)	Similar; the device weighs more than the predicate device but within predicate range of exoskeleton devices (26 lbs. – 66 lbs.).
Rechargeable Battery	Rechargeable lithium ion. 51.8 V, 10A peak current, 10A continuous current, 113Wh fully charged; 4 hours of continuous walking per charge	Rechargeable lithium ion. 33.3V, 36A peak current, 12A continuous current. 159Wh fully charged; 1.5 hours of continuous walking per charge	Similar; the phoenix battery is slightly smaller but provides the necessary power for the operation of the device. No additional safety or efficacy concerns.
Battery Charge Time	Maximum of 2 hours	Maximum of 4 hours	Similar; the Phoenix battery is able to be charged in a slightly faster period of time. No additional safety or efficacy concerns.
Expected Useable Life	5 years	5 years	Same
Training Program	Yes	Yes	Same
Certification Program	Yes	Yes	Same
User Feedback	Provides auditory feedback and LED indicators on top of hip unit, visible to the wearer	Provides vibratory feedback and LED indicators on top of hip unit, visible to the wearer	Similar; auditory feedback provides the user with critical safety information; both devices provide LED indicators to communicate information to the user. No additional safety or efficacy concerns.

Manufacturer	SuitX	Parker Hannifin	Significant Differences
Trade Name	**Phoenix Medical Exoskeleton**	**Indego®**	
Fall Detection and Mitigation	Detects posture and prevents user from standing up if improper posture is detected. Automatic User Interface timeout reduces the risk of falling due to accidental user inputs. Fall protection is provided by the Healthcare Professional/Physical Therapist (PT). Device does not have fall detection features.	Detects forward, backward, and sideways falling as it is happening; the device makes adjustments during the course of the fall to position the user for minimal risk of injury	Different; the Phoenix device will notify the user after detecting improper positioning to prevent the risk of injury during standup. While standing or walking, fall protection and mitigation is provided by the Healthcare Professional/ Physical Therapist (PT). No additional safety or efficacy concerns have been identified as both devices require a spotter to guard against falls.
Failsafe Feature	In the event of power failure – knees become locked and hips free (similar to typical passive leg braces)	In event of power failure – knees become locked and hips free (similar to typical passive leg braces)	Same
Operating Temperature	32°F to 88°F (0°C to 31°C)	32°F to 88°F (0°C to 31°C)	Same
Operating Humidity	30% to 75% RH	30% to 75% RH	Same
Electrical Safety Testing	Passed IEC 60601-1:2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	Passed ANSI/AAMI ES60601-1:2005/(R)2012	Similar; tested to newest version of the standard
Electromagnetic Compatibility Testing	Passed IEC 60601-1-2:2014 (4TH Edition)	Passed IEC 60601-1-2:2007	Similar; tested to newest version of the standard

8 Non-Clinical Performance Data

suitX completed a number of non-clinical tests to demonstrate the safety and effectiveness of the Phoenix™ and to establish substantial equivalence to the predicate device of this 510(k) submission. The Phoenix met all requirements for design characteristics, non-clinical performance testing, electrical safety and EMC/EMI testing, to confirm that the Phoenix device met the design inputs and specifications for the device.

The Phoenix passed all non-clinical testing in accordance with internal suitX requirements, national and international standards shown in Table 2 below to support substantial equivalence to the predicate device.

Table 2. Performance Testing by Technical Area

Technical Area	Test Completed	Results
Electrical Safety Testing	IEC 60601-1:2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	PASS
Electromagnetic Compatibility Testing	IEC 60601-1-2:2014 (4th Edition) AAMI/TIR69:2017 - Medical Devices - Risk Management of Radio-Frequency Wireless Coexistence	PASS
Battery Safety Testing	UN 38.3, ISO 62133	PASS
Thermal	IEC 60601-1:2005 (R2012)	PASS
Software Verification and Validation Testing	Software verification and validation testing per FDA Guidance and IEC 62304: • Conformance of software development life cycle for the Phoenix software system • Compliance to the requirements of the FDA guidance document for software contained in a medical device.	PASS
Maximum Torque Testing	Testing to verify the maximum continuous and peak torques that are applied at the knees and hips measured in Nm against defined specifications.	PASS
Cleaning Testing	Testing to verify the device can be cleaned using alcohol-based solution.	PASS
Component Lifecycle Testing	Verification that the device meets the requirements for the major mechanical subsystems to perform safely during the expected use between routine servicing in simulated normal use	PASS
Durability Testing	Performance testing designed to verify the device meets factors of safety defined in design input requirements	PASS
	Cyclic torque testing was conducted on various subsections of the device (e.g. hip, knee, spine).	PASS
	Cyclic impact fatigue loading of the device construct was completed.	PASS
Battery Life Cycle Testing	Testing performed for the batteries being cycled through normal use including measuring the full charge amount, capacity of battery, and cycle life over defined periods, according to the battery specifications	PASS
Storage and Transport Testing	Completed testing to support that the device is protected and not damaged during normal, routine shipping according to ISTA Standards for drop, compression, and vibration	PASS

The Phoenix device passed all testing stated above as shown by the acceptable results obtained.

9 Clinical Performance Data

A clinical study was performed with the investigational product, the Phoenix™, for assessing the mobility of persons with Spinal Cord Injury (SCI) while using the device. The study was conducted to evaluate the Phoenix device for safety and effectiveness in allowing persons with SCI who are non-ambulatory to poorly ambulatory to stand up and walk under a variety of conditions. The study was performed in compliance with Good Clinical Practices (GCP) with subjects enrolled in an IRB approved study that were consented for participation according to the intended use of the device, defined inclusion criteria, and defined exclusion criteria; with the purpose of meeting the study objectives.

The study objectives were defined as the following:

- Demonstrate that the Phoenix device is both safe and effective for the intended use for patients with SCI who are non-ambulatory or poorly ambulatory to stand up and walk under a variety of conditions.

- Participants with SCI Level T4 to L5 can safely complete transitional movements (stand up, turn, sit down) and walk using Phoenix with minimal contact assistance or Functional Independence Measure (FIM).

- Participants with SCI level T4 to L5 are able to achieve walking during the 10 Meter Walk Test (10MWT) and 6 Minute Walk Test (6MWT).

The clinical study was planned for and completed with 40 (forty) subjects. The subjects were required to complete a series of 20 (twenty) study sessions that included screening, fitting, evaluation, training with the device, as well as assessment from each session and outcome measurements. Assessments were conducted throughout the total number of sessions with final outcome measurements recorded at the completion of the study.

The outcomes measurements for the clinical study are summarized as follows:

- The mean FIM for the 10 Meter Walk Test (10MWT) was 4.6 (±0.50). Participants completed the 10MWT in 61.9 seconds (±34.64) on average with a mean speed of 0.12 m/s (±0.06). All participants were able to complete the 10MWT.

- The mean FIM for the 6-minute walk test was 4.37 (±0.49), indicating an acceptable level of functional independence during this assessment.

- The Timed Up-and-Go (TUG) Test measured the ability of the subject to perform transitional motions beyond just walking, i.e. standing up, sitting down, and turning. Of the 40 (forty) subjects that completed the study, 39 (thirty-nine) subjects were able to

complete with minimal contact assistance (FIM score of 4 or higher) and one (1) subject was able to complete with moderate contact assistance (FIM score of 3).

- Level of assistance was measured according to WISC-II and FIM scores during the study to provide a view of task-specific level of assistance needed while performing movements using the Phoenix device. The WISC-II scores for all subjects averaged mean scores of 8.60 (±2.19) for the final assessment during the study. The FIM scores as noted previously support that subjects were capable of managing all scenarios presented, which included using the device on concrete and carpet.

- Study participants were requested to complete multiple questionnaires during the study trial including a Modified Borg Rating of Perceived Exertion to capture the effort subjects felt to achieve basic level-ground walking. The averaged results of the assessment for indoor level ground walking at the end of their sessions was 3.3, which corresponds to an exertion level just above "moderate."

- Adverse Events (AE) reported during the study included minor instances of bruising. The causes attributed to these reported incidents were related to improper fitting or improper padding. These subjects were able to safely complete the study. There were no Unanticipated Adverse Events (UAE). The clinical study concluded that the Phoenix device is safe and effective for its intended use and the outcomes of the study met the stated objectives. The clinical trial supports the indication for use for enabling individuals with spinal cord injury at levels T4 to L5 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program.

10 Conclusion

The non-clinical and clinical testing information contained herein demonstrates the Phoenix™ performs according to its intended use. U.S. Bionics, Inc. (DBA suitX) considers the Phoenix (subject device) to be substantially equivalent to the legally marketed predicate device (K152416) noted herein and is safe and effective for its labeled intended use.