December 17, 2017

CYBERDYNE Inc.
Yohei Suzuki
Head of Production Department
2-2-1 Gakuen-Minami
Tsukuba, 305-0818 Jp

Re: K171909
Trade/Device Name: HAL for Medical Use (Lower Limb Type)
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL, HCC
Dated: November 29, 2017
Received: November 29, 2017

Dear Yohei Suzuki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171909

Device Name
HAL for Medical Use (Lower Limb Type)

Indications for Use *(Describe)*
HAL for Medical Use (Lower Limb Type) orthotically fits to the lower limbs and trunk; the device is intended for individuals with spinal cord injury at levels C4 to L5 (ASIA C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B), who exhibit sufficient residual motor and movement-related functions of the hip and knee to trigger and control HAL.

HAL is a gait training device intended to temporarily help improve ambulation upon completion of the HAL gait training intervention. HAL must be used with a Body Weight Support system. HAL is not intended for sports or stair climbing. HAL gait training is intended to be used in conjunction with regular physiotherapy.

In preparation for HAL gait training, the controller can be used while the exoskeleton is not donned to provide biofeedback training through the visualization of surface electromyography bioelectrical signals recorded.

HAL is intended to be used inside medical facilities while under trained medical supervision in accordance with the user assessment and training certification program

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Number: K171909

5.1 Applicant Information

Date Prepared:	December 15, 2017
Company Name and Address:	CYBERDYNE Inc. 2-2-1, Gakuen-Minami, Tsukuba-Shi, Ibaraki-Ken 305-0818 Japan
Contact Person:	Mr. Yohei Suzuki Head of Production Department Phone: +81-29-869-8453 FAX: +81-29-869-8443 Email: suzuki_yohei@cyberdyne.jp

5.2 Device Information

Device Name:	HAL for Medical Use (Lower Limb Type)
Common or Usual Name:	Powered Exoskeleton
Classification Name:	Powered Lower Extremity Exoskeleton (primary) Biofeedback Device (secondary)
Regulation Number:	21 CFR 890.3480 (primary) 21 CFR 882.5050 (secondary)
Device Class:	II
Product Code:	PHL
Secondary Product Code:	HCC

5.3.1 Legally Marketed Predicate Device

510(k) Number:	K131798
Primary Predicate	Primary
Applicant:	Argo Medical Technologies, Inc.
Device Name:	ReWalk
Regulation Number:	21 CFR 890.3480
Product Code:	PHL
Device Class:	II

5.3.2 Legally Marketed Reference Device

510(k) Number:	K971708
Applicant:	J & J Engineering Inc.
Device Name:	Physiological Monitoring & Biofeedback Training Device
Regulation Number:	21 CFR 882.5050
Product Code:	HCC
Device Class:	II

5.4 Device Description

HAL for Medical Use (Lower Limb Type) is a battery powered bi-lateral lower extremity exoskeleton that provides assistive torque at the knee and hip joints for gait training. HAL is comprised of a controller, a main unit, and sensor shoes. The device comes in 8 size variations (4 different leg lengths and 2 different hip widths) and weighs ~14 kg (30 lbs). The device uses legally marketed cutaneous electrodes (up to 18 electrodes) to record surface electromyography bioelectrical signals of the hip and knee extensor and flexor muscles when the device is used in Cybernic Voluntary Control (CVC) mode. This mode provides assistive torque at the corresponding joint (e.g., hip or knee) using surface electromyography bioelectrical signals that are processed using a propriety signal processing algorithm. The propriety processing algorithm allows the device to detect surface electromyography bioelectrical signals to control the HAL device in CVC mode and provide visualization of the surface electromyography bioelectrical signals during biofeedback training. The assistive torque can be adjusted using three parameters: sensitivity level, torque turner, and balance turner. The device can also provide two additional modes: Cybernic Autonomous Control (CAC) mode and Cybernic Impedance Control (CIC) mode. CAC mode provides assistive torque leg trajectories based on postural cues and sensor shoe measurements. CIC mode provides torque to compensate for frictional resistance of the motor based on joint motion. CIC mode does not provide torque assistance for dictating joint trajectories. A trained medical professional (i.e., physician, physical therapist, etc.) can configure, operate, and monitor the device during gait training to make adjustments as needed.

Patients must exhibit sufficient residual motor and movement-related functions of the hip and knee to trigger and control HAL. The patient must be supported by a Body Weight Support (BWS) system before donning the device and during device use. The BWS must not be detached from the patient before doffing this device. HAL is not intended to provide sit-stand or stand-sit movements. HAL is capable of gait speeds up to approximately 2 km/hour on level ground. HAL is not intended for sports or stairclimbing.

In preparation to using HAL, the controller can be used while the exoskeleton is not donned to provide biofeedback training through the visualization of surface electromyography bioelectrical signals recorded.

HAL is intended to be used in conjunction with regular physiotherapy. HAL is intended to be used inside a medical facility under the supervision of trained medical professionals who have successfully completed the HAL training program.

5.5 Indications for Use

HAL for Medical Use (Lower Limb Type) orthotically fits to the lower limbs and trunk; the device is intended for individuals with spinal cord injury at levels C4 to L5 (ASIA C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B), who exhibit sufficient residual motor and movement-related functions of the hip and knee to trigger and control HAL.

HAL is a gait training device intended to temporarily help improve ambulation upon completion of the HAL gait training intervention. HAL must be used with a Body Weight Support system. HAL is not intended for sports or stair climbing. HAL gait training is intended to be used in conjunction with regular physiotherapy.

In preparation for HAL gait training, the controller can be used while the exoskeleton is not donned to provide biofeedback training through the visualization of surface electromyography bioelectrical signals recorded.

HAL is intended to be used inside medical facilities while under trained medical supervision in accordance with the user assessment and training certification program.

5.6 Non-Clinical Performance Data

The subject devices demonstrate conformance with the following recognized standards:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012
- IEC 60601-1-2:2007
- IEC 60601-1-6:2013
- IEC 62133:2012, IEC 60335-1:2010, IEC 60335-2-29:2010 and ANSI/UL 1012:2010
- IEC 62304:2006 and IEC 62304:2015
- IEC 62366:2014

The subject device underwent bench testing as part of required performance verification and validation activities. Results show that the subject device has met pre-defined design and performance acceptance criteria. Results of all non-clinical testing support the safety and effectiveness of the subject devices.

Testing	Objective(s) and Study Design
Stopper Strength Test	<Objective(s)> To evaluate the durability of the mechanical stopper of the actuator that limits the maximum angle and verify that it endures the mechanical force that can be applied by the patient <Results> Conformance with acceptance criteria was maintained after 100 cycles. The mechanical stopper is expected to endure the impact in the joints.
Consecutive Landing Test	<Objective(s)> Test the durability of the mechanical and electrical systems of HAL against repeated impacts with the ground that occur while walking. Confirm whether missing parts, cracks/chips of the exterior, loosening of screws, abnormal noises, looseness, operational malfunctions, and loosening/detachment/deformation of the connectors do not occur after 5-years worth (service life of HAL) of consecutive impacts and vibrations. <Results> All 3 samples withstood 3,000,000 [cycles] of landing impact, and there were no missing parts, cracks/chips of the exterior, loosening of screws, abnormal noises, looseness, operational malfunctions, and

	loosening/detachment/deformation of the connectors. The assumed maximum steps of HAL is 1,000,000[cycles] so it is sufficiently durable.
Effective Output Test	<Objective(s)> This test consists of two tests, each with different objectives below: A. Effective torque test: To verify that the actuator meets specifications for effective output torque by measuring the effective output torque to the input (electrical current). B. Maximum angle velocity test: To verify that the maximum angular velocity, generated when maximum torque is output, is within the range of that tolerable by the human knee joint. <Results> A. Effective torque output test: The output was verified to meet the specification. It was also within the range required by risk management. B. Maximum angular velocity test: The angular velocity was verified to be within a range that the human body can tolerate.
Driving Parts Performance Test	<Objective> To Measure the actual torque output against the torque output intended by the control algorithm, and confirm that it meets the performance criteria. <Results> The test results show that the actual torque output compared to the torque output intended by the control algorithm falls within the criteria range, and the performance of the driving parts meets the expected results.
Joint angle measurement	<Objective> To test the accuracy of joint angle sensing. <Results> Accuracy of joint angle measurement was verified to meet specification.
Body trunk absolute angle measurement	<Objective> To test the accuracy of body trunk absolute angle sensing. <Results> The measurement results show that the body trunk absolute angle measurement of the device can sufficiently detect the stable posture in the forward/backward directions of the patient, thus ensuring the safety and effectiveness of the device.
Plantar load measurement	<Objective> To test the accuracy of plantar load measurement. <Results> The measurement results show that the plantar force measurement of the device can sufficiently detect the planting and lifting of the sole, to enable the device to determine what phase (swing/support) each leg is in, thus ensuring the safety and effectiveness of the device.
Surface Electromyography Bioelectrical signal measurment performance	<Objective> To test the accuracy of surface electromyography bioelectrical signal measurement performance. The tests included an assessment of input impedance, common-mode rejection ratio, and frequency characteristics. <Results> Accuracy for all measurements were verified to meet specifications.
Ankle Durability	<Objective>

Test	Test the durability of the mechanical systems of the ankle parts against repeated impacts in a twisting direction, simulating impacts applied to the parts during a turning movement. Confirm whether missing parts, cracks/chips of the exterior, loosening of screws, abnormal noises, looseness do not occur after 5-years worth (service life of HAL) of consecutive impacts. <Results> All 3 samples withstood 300,000 [times] of impact, and there were no missing parts, cracks/chips of the exterior, loosening of screws, abnormal noises, looseness. The ankle part of the device is sufficiently durable.

5.7 Clinical Performance Data

<DE-01 Clinical Study Summary> [Pilot Study]

Site	BG University Hospital Bergmannsheil
Patient Population	Chronic spinal cord injury (97.2±88.4 months since injury)
Objective	To determine whether locomotor training with the exoskeleton HAL® is safe to use and can increase functional mobility in chronic paraplegic patients after SCI.
Inclusion Criteria	• traumatic SCI with chronic incomplete paraplegia or complete paraplegia after lesions of the conus medullaris/ cauda equine with zones of partial preservation (ZPP). • patients must present motor functions of hip and knee extensor and flexor muscle groups in order to be able to trigger the exoskeleton.
Exclusion Criteria	• Non traumatic SCI • pressure sores • severe limitation of range of motion (ROM) regarding hip and knee joints • cognitive impairment • body weight > 100kg • non-consolidated fractures • mild or severe heart insufficiency
Duration	June ~ September 2013
Design and Protocol	<Design> Study method: Interventional Basic Design: Single arm Randomization: Non-randomized Blinding: Open (no blinding) Control: Uncontrolled <Method> During this study, the patients underwent a BWSTT (Body Weight Supported Treadmill Training) five times per week using the HAL. The treadmill system (Woodway USA, Inc., Waukesha, WI, USA) includes a body weight support system with a harness. During treatments, the velocity of the treadmill was set individually between comfortable and maximum speed tolerated by the patients. Approximately 50% of each patient's body weight needed to be supported by the harness system, individually reduced during the following sessions as tolerated without substantial knee buckling or toe drag.

<table>
<tr><td></td><td>The patients underwent a 90-day period of HAL training (five per week), including a mean number of sessions of 51.7565.6. The training was performed on a treadmill with individually adjustable body weight support and speed, recording walking speed, time, and distance. It included a 10-m walk test (10MWT) before and after each session and regular physiotherapy that lasted approximately 90 minutes. The training was supervised by a physiotherapist and a medical doctor.</td></tr>
<tr><td>Intervention</td><td>90 days (5 times/week)</td></tr>
<tr><td>Sample size (N)</td><td>8</td></tr>
<tr><td>Results</td><td>Significant improvements have been especially shown in the functional abilities without the HAL for over ground walking obtained in the 6MWT and the 10MWT. While the TUG-Test was not significant after Bonferronni correction (α = 0.00625), the results show a trend toward improvement, and an increase in the WISCI II score of three patients is also promising.

<Functional Measures>

<table>
<tr><th>Endpoint</th><th>n</th><th>Average Improvement</th><th>Paired T-test</th><th>Wilcoxon Signed-Rank Test</th><th>95% CI</th></tr>
<tr><td>10MWT (speed)</td><td>8</td><td>0.23±0.14 m/s</td><td>P = 0.0025</td><td>P < 0.01</td><td>[0.13, 0.33]</td></tr>
<tr><td>TUG test</td><td>8</td><td>17.16±19.01 s</td><td>P = 0.0379</td><td>P < 0.02</td><td>[3.99, 30.33]</td></tr>
<tr><td>6MWT (distance)</td><td>8*</td><td>93.25±39.40 m</td><td>P = 0.0003</td><td>P < 0.01</td><td>[65.95, 120.55]</td></tr>
<tr><td>WISCI II</td><td>8</td><td>1.125</td><td>P = 0.0796</td><td>N/A</td><td>[0.05, 2.20]</td></tr>
</table>

*Only three patients were able to walk for 6 minutes before training, but all 8 patients were able to walk for 6 minutes after the intervention.</td></tr>
<tr><td>Adverse Events</td><td>• No serious/severe adverse events occurred/observed
• Two cases of mild adverse events were observed. In both cases, skin redness due to electrodes was observed but patients recovered naturally shortly after electrodes were removed.</td></tr>
<tr><td>Manuscripts</td><td>• The Spine Journal, titled “Voluntary driven exoskeleton as a new tool for rehabilitation in chronic spinal cord Injury – A pilot study”</td></tr>
</table>

<DE-02 Clinical Study Summary>

Site	BG University Hospital Bergmannsheil
Patient Population	Chronic spinal cord injury (6.85±5.12 years since injury), SCI C2-L5, ASIA D, C, and ASIA A with Zones of Partial Preservation
Objective	To examine functional outcomes as a function of age and lesion level in patients with chronic incomplete SCI (iSCI) or chronic complete SCI (cSCI) with zones of partial preservation (ZPP) by using the HAL as a temporary training tool.
Inclusion Criteria	• SCI with chronic incomplete paraplegia or tetraplegia at any spinal cord lesion level (ASIA C/D) or chronic complete paraplegia (ASIA A) at lesion levels T11 or lower, AND

	• patients must present motor functions of hip and knee extensor and flexor muscle groups in order to be able to trigger and control the exoskeleton.
Exclusion Criteria	• Absence of residual motor functions in the lower extremities • pressure sores • severe limitation of range of motion (ROM) regarding hip and knee joints • cognitive impairment • body weight > 100kg • non-consolidated fractures • epilepsy • severe heart insufficiency
Duration	January 2012~ June 2016
Design and Protocol	<Design> Study method: Interventional Basic Design: Single arm Randomization: Non-randomized Blinding: Open (no blinding) Control: Uncontrolled <Method> During this study, the patients underwent a BWSTT (Body Weight Supported Treadmill Training) five times per week using the HAL. The patients underwent a 90-day period of HAL training (five per week), including a mean number of sessions of 58.78±2.37. The training was performed on a treadmill with individually adjustable body weight support and speed, recording walking speed, time, and distance. A 10-m walk test (10MWT) without the HAL was performed before and after each session in addition to regular physiotherapy. Training effects (e.g., 10 MWT, 6 MWT, WISCI-II) were assessed at the baseline, week 6, and week 12, without HAL assistance (i.e., exoskeleton is not worn during testing).
Intervention	90 days (5 times/week)
Sample size (N)	55
Results	Overall, a time reduction of 47% in the 10MWT, self-selected speed (10MWTsss) (< 50 years = 56% vs ≥ 50 years = 37%) and an increase of 50% in the 6MinWT were documented. Age had a nonsignificant negative influence on the 10MWTsss. Despite a few nonsignificant subgroup differences, participants improved across all tests. Namely, patients with iSCI who had spastic motor behavior improved to a nonsignificant, lesser extent in the 6MinWT. The level of assistance captured in the Walking Index for Spinal Cord Injury II (WISCI II) testing pre and post gaiting training reflects the test setup used during 10 MWT test pre and post gait training, respectively. There were instances where the amount of assistance used during the 6 MWT test differed slightly from the WISCI-II Score. The results of the intervention were compared to the established MCID. The average 10MWT improvement was 0.20 m/s with 95% confidence inter of [0.16, 0.25], a value that is more than three times the MCID of 0.06 m/s. The average 6 MWT improvement was 48.53m with 95% confidence interval of [37.35, 59.71], a value that is also larger than the MCID of 36m. It can therefore be said that the improvements

<table>
<tr><td></td><td>seen in both the 10 MWT and the 6 MWT are clinically significant. Furthermore, the WISCI II scores showed a mean gain of 1.69 levels. At the end of the study, 24 of 55 patients (43.6%) were less dependent on walking aids.

<Functional Measures>

<table>
<tr><th>Endpoint</th><th>n</th><th>Pre- (measurement without HAL)</th><th>Post- (measurement without HAL)</th><th>p</th></tr>
<tr><td>10MWT (speed)</td><td>55</td><td>70.45±61.50 s</td><td>35.22±30.80 s</td><td><0.001</td></tr>
<tr><td>6MWT (distance)</td><td>55</td><td>97.81±95.80 m</td><td>146.34±118.13 m</td><td><0.001</td></tr>
<tr><td>WISCI II</td><td>55</td><td>9.35±5.12</td><td>11.04±4.52</td><td><0.001</td></tr>
</table>
</td></tr>
<tr><td>Adverse Events</td><td>• Five cases of mild adverse events were observed. In all cases, skin redness due to electrodes was observed but patients recovered naturally shortly after electrodes were removed.
• One subject had fallen from his wheelchair while at home, and suffered a femoral neck fracture. The incident was not related to the use of the device, and the subject was dropped from the study due to inability to continue.
• One subject had a pressure ulcer on her left ankle that developed while horseback riding. The incident was not related to the use of the device, and the treatment was suspended until the ulcer healed.</td></tr>
<tr><td>Manuscripts</td><td>JNS Neurosurgical Focus, titled “Against the odds: what to expect in rehabilitation of chronic spinal cord injury with a neurologically controlled Hybrid Assistive Limb exoskeleton. A subgroup analysis of 55 patients according to age and lesion level ”</td></tr>
</table>

5.8.1 Comparison of Intended Use/Indications for Use

Indications for Use	
Subject Device	**Predicate Device**
HAL for Medical Use (Lower Limb Type)	**ReWalk (K131798)**
HAL for Medical Use (Lower Limb Type) orthotically fits to the lower limbs and trunk; the device is intended for individuals with spinal cord injury at levels C4 to L5 (ASIA C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B), who exhibit sufficient residual motor and movement-related functions of the hip and knee to trigger and control HAL.	The ARGO ReWalk orthotically fits to the lower limbs and part of the upper body and 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

HAL is a gait training device intended to temporarily help improve ambulation upon completion of the HAL gait training intervention. HAL must be used with a Body Weight Support system. HAL is not intended for sports or stair climbing. HAL gait training is intended to be used in conjunction with regular physiotherapy. In preparation for HAL gait training, the controller can be used while the exoskeleton is not donned to provide biofeedback training through the visualization of surface electromyography bioelectrical signals recorded. HAL is intended to be used inside medical facilities while under trained medical supervision in accordance with the user assessment and training certification program	functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk is not intended for sports or stair climbing.

5.8.2 Similarities and Differences of Intended Use/Indications for Use (IFU)

The subject device is intended for an expanded range of Spinal Cord Injury patients when compared to the predicate device. In addition to the training requirements, contraindication, warnings, precautions, the subject device mitigates risks of device use by:

- Limiting device use to inside medical facilities
- Requiring the use of a Body Weight Support system
- Requiring vital capacity and pulse oximetry testing for C5-C4 SCI patients before and after device use
- Requiring blood pressure and heart rate monitoring for all patients prior to standing, while standing, and after walking

These requirements do not raise new questions of safety and effectiveness.

In preparation for using HAL, the controller can be used while the exoskeleton is not donned to provide biofeedback training through the visualization of surface electromyography bioelectrical signals recorded at the hip and knee extensor and flexor muscles. The biofeedback training is provided in preparation to using HAL and does not raise new questions of safety or effectiveness.

HAL is a gait training device intended to temporarily help improve ambulation upon completion of the HAL gait training intervention. The effectiveness of HAL was demonstrated in two clinical studies (see section 5.7 above), the first with 8 subjects and the second with 55 subjects. All subjects were chronic (> 1 year since trauma) SCI patients with injuries ranging from C2-L5, ASIA D, C, B and ASIA A with Zones of Partial Preservation.

The effectiveness was measured by collecting data on 10 meter walk tests (10 MWT), 6minute walk tests (6 MWT), and WISCI-II tests, all measured without wearing the HAL device. The endpoints were collected at start of the study (week 0), midpoint (week 6) and upon completion of the study (week 12). The results suggest a statistically significant improvement in the gait related outcome measures collected. In contrast to the predicate device's IFU statement for device worn ambulation, the subject device's IFU statement for gait training required clinical data to support the effectiveness of the gait training intervention (i.e., testing of ambulation while not wearing the exoskeleton). The studies (see section 5.7 above) support the Indications for Use and a decision of substantial equivalence.

5.9.1 Comparison of Technological Characteristics

Device	Subject Device (HAL for Medical Use)	Predicate Device (ReWalk K131798)
Body Coverage	• Worn over legs and around hips and lower torso.	• Worn over legs and around hips and lower torso
Patient Height	150-190 cm	160-190 cm
Patient Weight	40-100 kg	Maximum 100 kg
Intended Environment	• Flat surface of medical facilities (indoor only) • Must be used in combination with BWS systems.	• Home use (includes outdoor) • Used with canes (device component)
Intended Users	Medical professionals that have completed designated training program to use the device	Those that have completed designated training program (includes medical professionals and nonprofessionals like companions or family members)
Hardware and Main Components	The system consists of three major components: • Controller • Main unit • Sensor shoes	The system consists of three major components: • Remote control communicator • Exoskeleton • Backpack
Device Variations	• 8 different size/shape variations: 4 leg lengths, 2 waist widths. • Sensor shoes are available in sizes of 23, 24, 25, 26, 27, 28, 29, 30 cm	• The predicate comes in 2 different purpose variations: R (rehabilitation) and P (personal). • The R type has 5 variations for different pelvic band widths. The P type has only one pelvic band width.
Device Lifetime	5 Years	5 Years

Device	Subject Device (HAL for Medical Use)	Predicate Device (ReWalk K131798)
Power Sources	Lithium-ion battery	• Main battery: Lithium ion battery • Auxiliary battery: Lithium polymer battery
Range of Motion	• Hips: 120° flexion to -20° extension • Knee: 120° flexion to -6° extension	• Hips: 104° flexion to -34° extension • Knee: 112° flexion to 2° extension
Method of Control	• Surface electromyography Bioelectrical signals at knee and hip extensor and flexor muscles (CVC mode), Attached controller used by medical professional, Postural and Shoe sensor cues for movement	• Remote control worn on wrist to change modes; postural cues for stepping
Modes of Operation	• CVC (Cybernic Voluntary Control) • CAC (Cybernic Autonomous Control) • CIC (Cybernic Impedance Control) Can be selected for each joint (right/left hip/knee joints)	• SIT-TO-STAND • STAND • WALK • STAND-TO-SIT • MANUAL • BYPASS
Safety Features	• 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 initiate incorrect task changes	• System fault at power up • Main computer failure • Incorrect operational mode selection • Excessive joint flexion/extension angles • Loss of balance while rising from a chair • Misstep or obstacle • Complete loss of power • Loss of communication between remote and main computer
Fall Prevention Measures	BWS systems	Crutches
Bench Testing	• Durability of mechanical stopper: applicant test • Durability of ankle part: applicant test • Consecutive Landing: applicant test • Effective output: applicant test	• Worst Case Loading of Knee Joint: Sponsor study • Worst Case Loading of Hip Joint: Sponsor study • Structural analysis of frame: FEA analysis • Software testing: Verification,

Device	Subject Device (HAL for Medical Use)	Predicate Device (ReWalk K131798)
	• Software testing: Verification, validation & hazard analysis	validation & hazard analysis
Operating Temperature	• 50° to 86° F (10° to 30° C)	• 10° to 95° F (-12° to 35° C)
Performance Standards	• Electrical Safety: AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012 • Electromagnetic Compatibility: IEC 60601-1-2: 2007 • Usability: IEC 60601-1-6: 2010 and IEC 62366: 2014 • Battery Safety: IEC 62133: 2012, IEC 60335-1: 2010, IEC 60335-2-29: 2010 and ANSI/UL 1012: 2010 • Software: IEC 62304: 2015	• Electrical Safety: IEC 60601-1: 2005 • Electromagnetic Compatibility: IEC 60601-1-2: 2007 • Battery testing: EMC/EMI certificate • Flammability: ISO 7176-16: 2012
Training	• CYBERDYNE-developed program for medical professionals • The device is intended to be used only in medical facilities for HAL gait training. • Must be used under the supervision of a trained medical professional in accordance with the user assessment and training certification program	• Tier based program • Manufacturer developed program consisting of 4 tiers and 3 levels of tests for users and caregivers or companions
Clinical Studies	• There are 2 studies conducted on spinal cord injury subjects. The studies cover the indications for use of the device. Both effectiveness and safety are measured in the study and statistical analysis has been performed for results on effectiveness. • The studies were both non-comparative and non-randomized. • All subjects were chronic (> 1 year since trauma) SCI patients with injuries ranging from C2-L5, ASIA D, C, B and ASIA A with Zones of Partial Preservation • The sample size of the studies are 8 and 55 subjects,	• There are 3 studies reported, all conducted on spinal cord injury patients. • All studies were non-comparative and non-randomized. • The sample size of the studies are: 7 (6 completed measurements), 24 (20 completed measurements) and 7 • The effectiveness is primarily measured by 6 minute walk tests and 10 meter walk tests. • The safety is primarily measured by reporting of no falls, and minor incidents that include blisters, skin tears, bruises, lesions, edema and hematoma.

Device	Subject Device (HAL for Medical Use)	Predicate Device (ReWalk K131798)
	respectively • The effectiveness is primarily measured by 10 meter walk tests, 6 minute walk tests, and WISCI-II tests, all measured without wearing the HAL device. The results suggest a statistically significant improvement in gait related outcome measures. • The safety of the device is primarily measured by SAE and AE occurrences. There were no SAE reported. AE's included reports of minor incidents that included: pain due to pressure from device parts that were managed by adjusting a better fit, skin irritation from electrodes and chafed feet due to wrong shoe size. • Long term use of over 12 weeks (60 treatment sessions) has not been clinically tested.	
Special Controls	Complies with special controls per 21 CFR 890.3480, as applicable	Complies with special controls per 21 CFR 890.3480, as applicable

5.9.2 Similarities and Differences of Technological Characteristics

Similarities are seen in patient height, weight, device lifetime, power sources, performance standards, compliance with special controls. Differences are seen in intended environment, intended users, hardware, device design, modes of operation, safety features, fall prevention measures, and bench testing.

The subject device demonstrates substantial equivalence to the predicate device by implementing mitigations to address design differences, including but not limited to: requiring a Body Weight Support (BWS) system, restricting device use to inside medical facilities, performing additional bench tests to validate exoskeleton design and control systems, and demonstrating conformance to similar recognized consensus standards (e.g., AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 62133) to support the electrical safety and electromagnetic compatibility of the subject device. The clinical studies provided support a decision of substantial equivalence by demonstrating the subject device can be used as safely as the predicate device; as well as substantiating the claims made in the Indications for Use statement (see section 5.8.2 above for additional information).

5.10 Conclusions

Based on the above information and comparisons of intended use, indications for use, and technological characteristics, despite the differences described above for which we do not consider to raise different questions of safety and effectiveness, we believe that the subject device is as safe and effective as, and therefore substantially equivalent to, the identified predicate device.