May 7, 2024

Cyberdyne Inc.
Yohei Suzuki
Official Correspondent
2-2-1 Gakuen-Minami
Tsukuba, Ibaraki 305-0818
Japan

Re: K233695
Trade/Device Name: Medical HAL Lower Limb Type (HAL-ML)
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL, HCC
Dated: April 9, 2024
Received: April 9, 2024

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233695

Device Name

Medical HAL Lower Limb Type (HAL-ML)

Indications for Use *(Describe)*

Medical HAL Lower Limb Type orthotically fits to the lower limbs and trunk;
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.

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);
- post stroke paresis
- paraplegia due to progressive neuromuscular diseases (spinal muscular atrophy, spinal and bulbar muscular atrophy, amyotrophic lateral sclerosis, Charcot-Marie-Tooth disease, distal muscular dystrophy, inclusion body myositis, congenital myopathy, muscular dystrophy)
-cerebral palsy and are 12 years or older
-spastic paraplegia caused by either HTLV-1 Associated Myelopathy (HAM) or hereditary spastic paraplegia (HSP)
who exhibit sufficient residual motor and movement-related functions of the hip and knee to trigger and control HAL.

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 healthcare 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K233695

510(k) Summary

Prepared on: 2024-04-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	CYBERDYNE Inc.
Applicant Address	2-2-1 Gakuen-minami Tsukuba Ibaraki 305-0818 Japan
Applicant Contact Telephone	+81298698453
Applicant Contact	Mr. Yohei Suzuki
Applicant Contact Email	suzuki_yohei@cyberdyne.jp

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Medical HAL Lower Limb Type (HAL-ML)
Common Name	Powered lower extremity exoskeleton
Classification Name	Powered Exoskeleton
Regulation Number	890.3480
Product Code	PHL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201559	HAL for Medical Use (Lower Limb Type)	PHL

Device Description Summary

21 CFR 807.92(a)(4)

Medical HAL Lower Limb Type is a battery powered bi-lateral or uni-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 30 size variations (variation same as predicate: 3 different leg configurations, 4 different leg lengths, 2 different waist widths >> total 24. New size variation: 3 different leg configurations, 1 leg lengths, 2 different waist widths >> total 6) and weighs ~9.5 kg (21 lbs). The main difference between the Model ML05 and ML07 is the leg lengths. ML05 has S,M, L, XL sizes, while ML07 has 2S sizes. The device uses legally marketed electrodes (up to 18 electrodes) to record 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 tuner, and balance tuner. 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.

It is thought that one of the causes of diseases of the brain, nerves, and muscles lies in an abnormality of the signal transmission loop of the brain/nervous system between the brain and the peripherals that normally allows the body to function appropriately.

All Medical Cybernic Systems, including HAL, are designed to detect and adjust the patient's neurological information in a way that allows the device to assist with the appropriate function of the body. Through repeated activity that is synchronized with the brain's neural signal of motor intent, the patient's physical function gradually improves.

More specifically, in order to allow the body to appropriately function even if the signal detected at the periphery is too faint to elicit actual muscle movement, an MD can intervene by tuning the parameters embedded in the Medical Cybernic System. This intervention enables the Medical Cybernic System to realize the movement intended by the patient in place of the patient's muscles. Even if the muscles barely function, repetition of neurologically-controlled voluntary movement and walking treatment has been shown to improve ambulation.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Medical HAL Lower Limb Type orthotically fits to the lower limbs and trunk;
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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);
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who exhibit sufficient residual motor and movement-related functions of the hip and knee to trigger and control HAL.

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 healthcare facilities while under trained medical supervision in accordance with the user assessment and training certification program.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The device has additional diseases as target populations and consequently has different indications for use in comparison to the predicate device.
The additional diseases are "cerebral palsy" and "spastic paraplegia caused by either HTLV-1 Associated Myelopathy (HAM) or hereditary spastic paraplegia (HSP).
The applicant has submitted clinical data to support the safety and efficacy of the treatment with the device for patients with these diseases. The level of evidence is equivalent to the other diseases already reviewed in K201559. Therefore the difference does not raise new questions regarding the safety and effectiveness of the device and do not constitute a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device expands the indication for use (target disease) and expands the height range of intended patients enabling smaller patients to use the device. The comparison of target diseases and patient physique are listed below:

<Target diseases>
- Spinal cord injury: Intended for both the subject and predicate devices
- Post stroke paresis: Intended for both the subject and predicate devices
- Progressive neuromuscular diseases: Intended for both the subject and predicate devices
- Cerebral palsy: Newly intended for the subject device (Not intended for the predicate device)
- Spastic paraplegia caused by either HTLV-1 Associated Myelopathy or hereditary spastic paraplegia: Newly intended for the subject device (Not intended for the predicate device)

<Patient physique>

- Weight: 15kg-100kg for the subject device, and 40kg-100kg for the predicate device.
- Height(approx.): 100cm-190cm for the subject device, and 150cm-190cm for the predicate device.

The subject device adds a smaller variation to enable use by patients who were too small (short) to fit the predicate device. The additional variation is based on the same concept and principle, but is assembled using different parts that reflect the difference in device size.

Performance testing on electrical safety and EMC were newly conducted for the additional variation where different questions about safety may arise. The selection of the device size variation depends completely on the physical size of the patient, and does not depend on the disease.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following nonclinical test were newly submitted for the additional size variation device. FDA guidance documents and recognized consensus standards were not used/referenced.
-Maximum angle velocity
-Torque output
-Angle measurement performance
-Trunk absolute angle measurement performance
-Plantar force measurement performance
-BES input impedance
-BES measurement performance (CMRR)
-BES measurement performance (Frequency characteristics)

The safety and effectiveness of the subject device is demonstrated through the following clinical evaluation procedure for each of the 5 indication groups (A: spinal cord injury (K171909 cleared, and included in K201559), B: cerebrovascular disease (K201559 cleared), C: progressive neuromuscular disease (K201559 cleared), D: cerebral palsy (new) and E: spastic paraplegia (new)).
After evaluating the results for the 5 groups, we conclude that:
A. The device is sufficiently safe when used under general and special controls described in this submission; and
B. The evaluation results are sufficient to support the claims identified in the Indications for Use for this submission.

The nonclinical and clinical tests submitted demonstrate that the device is as safe and as effective, and performs as well as the legally marketed device cleared as K201559.