

News

# December 19, 2017 CYBERDYNE,INC.

### CYBERDYNE obtained marketing clearance from U.S. FDA for Medical HAL as a medical device

~Introducing Medical HAL, the world's first robotic medical device that has been shown to improve the patient's own ability to walk, to the U.S. market~

On December 17 EST, CYBERDYNE, INC. [Tsukuba, Ibaraki, CEO: Yoshiyuki Sankai (the "Company")] obtained marketing clearance from the United States Food and Drug Administration ("FDA") for its HAL for Medical Use [Lower Limb Type]("Medical HAL"). The Medical HAL is known as the world's first robotic medical device, but this marketing clearance by the FDA shows that the therapeutic effects of the device has been acknowledged by the FDA. Medical HAL is already marketed as a medical device in Japan and in the EU, and this marketing clearance allows the device to reach patients in the three largest markets for advanced medicine.

## Background

Anticipating the effects on business developments after obtaining medical device marketing clearance in the US, the Company had continued to clarify and explain the designed purpose, technical characteristics and clinical benefits of Medical HAL. More specifically, the Company explained that Medical HAL is considered to be an innovative Cybernic Treatment\*1 device that attempts to actively improve and regenerate the function of the patient's own brain-nerve-physical systems, instead of an orthosis that physically supports the patient to walk or a robot that repeatedly performs specific movements for its patients. As a result of these continued discussions with the FDA, the Company submitted the application on June 19, 2017 (EST) to obtain marketing clearance for Medical HAL. FDA received the application on June 26, 2017 (EST).

#### Differences between Medical HAL and other devices

Many aspects of Medical HAL regarding indications, technological characteristics and clinical effectiveness for spinal cord injured patients, have been reflected in this marketing clearance. The main points regarding the characteristics of Medical HAL are set forth below.

• The Indication for Use: Medical HAL is a gait training device intended to temporarily help improve ambulation upon completion of the HAL gait training intervention.

Note 1: Other devices in the category are intended to enable individuals to perform ambulatory



functions while it is worn.

Note 2: Long term use of over 12 weeks (60 treatment sessions) has not been clinically tested and therefore the term "temporarily" is used.

- Technical Characteristics: Medical HAL mainly uses surface electromyography bioelectrical signals that reflect the muscle and nerve information of the patient to control the movements.
   Note: Other devices in the category use postural cues, weight shift, remote control, etc. to control the movements.
- The therapeutic effects: The results of HAL gait training intervention suggest a statistically significant improvement in the gait related outcome measures collected without wearing HAL, and clinical significance was acknowledged.

## Device Classifications of FDA

Definitions of the product classification were revised by the FDA. The classification of Physical Medicine Devices §21 CFR 890.3480, including its definition, was expanded to encompass the difference between Medical HAL and other devices in the category.

Furthermore, Medical HAL became the only medical device that is classified under the combination of these two categories, Neurological Devices §21 CFR 882.5050 and Physical Medicine Devices §21 CFR 890.3480.

## Schedule

Following the marketing clearance from the FDA, the Company will promptly comply with necessary procedures in order to develop its business in the US related to Medical HAL. More specifically, in accordance with the news release that was announced on November 14, 2017, the Company will establish a joint venture, Cybernic Treatment Center in Florida with Brooks Rehabilitation (Jacksonville, Florida, USA, CEO: Douglas M Baer) as a base of Cybernic Treatment service with Medical HAL to spread it across the world's largest US market.

The Company notes that, in order to obtain marketing clearance, data from the German clinical study supported by New Energy and Industrial Technology Development Organization (NEDO), Japan, was partially used. Furthermore, the Company utilized the safety evaluation method on Medical HAL, which was developed by Impulsing Paradigm Change through Disruptive Technologies Program (ImPACT program) hosted by the cabinet office of Japan.



Link:

FDA : 510(k) Premarket Notification
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K171909
\*For more details of the marketing clearance please refer to the summary document that will be disclosed by the FDA on a later date.

Establishment of Cybernic Treatment Center in Florida, USA ~basic agreement on joint business project, signed with one of the busiest rehabilitation hospital group in the U.S.~ https://www.cyberdyne.jp/wp\_uploads/2017/11/Brooks-release\_ENG.pdf (November 14, 2017)

\*1 Cybernic Treatment is described as "Functional Regenerative Medicine" realized by devices like Medical HAL that are developed using Cybernic Technology, and it is an innovative treatment technology that promotes the functional improvement/regeneration of the brain-nerve-physical systems. Medical HAL establishes interactive biofeedback by moving according to intension-based motion information from the brain-nervous system and activating sensory systems like muscle spindle fibers to form a neural loop between the brain-nerve system and the musculoskeletal system. Even if the patient is unable to generate enough muscle strength to move due to motor dysfunction, the treatment is able to repeatedly realize actual movement that is in sync with the motion intent of the brain while avoiding excessive burden on the brain-nerve-muscle systems, thus making functional improvement/regeneration possible. Clinicians can intervene by tuning the many adjustable parameters related to the patient's motor and neurological information built into the device, in a way that appropriately circulates the patient's neurological information through the neural loop between the brain-nerve system and the musculoskeletal system. Treatment with Medical HAL has been approved by the regulatory authorities in Japan and has been listed as a new treatment procedure that is distinct from other traditional rehabilitation procedures, with a different reimbursement price. Cybernic Treatment is not limited to Medical HAL and can be administered by other Medical Cybernic Systems that take on various forms using Cybernic Technology.





Image of Cybernic Treatment using the Medical HAL (Cyberdyne Care Robotics, Bochum, Germany)