November 25th, 2015
CYBERDYNE Inc.

HAL for Medical Use (Lower Limb Type) Received Approval to be Manufactured and Sold as a Medical Device by the Ministry of Health, Labour and Welfare

CYBERDYNE Inc. (Headquarters: Tsukuba, Ibaraki; President and CEO: Dr. Yoshiyuki Sankai; hereinafter referred as "CYBERDYNE"), received approval to manufacture and sell Japan's first robot therapeutic device "HAL for Medical Use (Lower Limb Type)" (hereinafter referred as "HAL for Medical Use"), as a medical device by the Ministry of Health, Labour, and Welfare on November 25th, 2015. Furthermore, preparations toward the treatment's coverage under public medical insurance are under way.

HAL for Medical Use is the world's first robot therapeutic device that aims to improve the walking function of patients through repetitive ambulatory training exercises using the device's support of their lower limb movements based on the wearer's bioelectric signals ("BES"). The device's safety and efficacy of slowing down the advancement of disease for patients with slowly progressing neuromuscular diseases (refer to the product overview) were recognized through clinical tests, and the device received its approval as Japan's first robot therapeutic device.

HAL for Medical Use is equipped with the motion principle developed by University of Tsukuba's Dr. Yoshiyuki Sankai (CEO of CYBERDYNE), which includes Cybernic Voluntary Control (control based on bioelectric signals derived from brain and nerve signals that reflect the patient's intent to move), Cybernic Autonomous Control (control based on preprogrammed movements taken from motion data of healthy walkers), and Cybernic Impedance Control (control that compensates for the device's mass and inherent viscous friction of the actuators to minimize discomfort from wearing the device). Because these controls can be set individually for each joint of the device, combining to form a Cybernic hybrid control structure, the device also features the technological attribute of allowing for detailed adjustments based on the patient's condition, physical functions, and training environment.

HAL for Medical Use had received a designation as a medical device for orphan diseases, and as a target of prioritized deliberations, CYBERDYNE had been aiming for approval within 9 months of its application submission[*1]. As a result of prioritized deliberations, the deliberation period was reduced by 4 months from the normal 12 month period, and on this occasion, CYBERDYNE was able to receive the approval within 8 months since the submission of the application on March 25, 2015[*2]. The Pharmaceutical Affairs and Food Sanitation Council (Medical Equipment and External Diagnosis Subcommittee) had given its consent on November 10, 2015[*3], and an official approval was announced today.

Henceforth CYBERDYNE plans to proceed with its application for public medical insurance coverage for treatment with HAL for Medical Use.

Furthermore, in order to expand the application for HAL for Medical Use from the approved neuromuscular diseases to spinal cord diseases, CYBERDYNE has implemented clinical trials for spastic paraplegia diseases like HTLV-1 associated myelopathy (HAM) since September 2014[*4].

[Product Summary]
Brand Name: HAL for Medical Use (Lower Limb Type)
Generic Name: Bioelectric Signal Reaction Type Motor Function Improvement Device (newly established)
Date of Receipt of Manufacturing and Sales Approval: November 25, 2015
Approval Number: 22700BZX00366000
Intended Use and Indication for Use:
<Intended Use>
This product was intended to be used by patients with slowly progressive neuromuscular disease mentioned below, to improve their walking function by intermittently wearing this product. This device aims to improve the patient's walking function through repeated ambulatory exercise training with the device's support of their lower limb movements based on the wearer's bioelectric signals.
<Indication for Use>
The target patients are patients whose walking functions have been impaired due to slowly progressive neuromuscular disease. Specifically, target patients are diagnosed with a slowly progressive neuromuscular disease of either spinal muscular atrophy (SMA), spinal and bulbar muscular atrophy (SBMA), amyotrophic lateral sclerosis (ALS), Charcot-Marie-Tooth disease (CMT), distal myopathy, inclusion body myositis (IBM), congenital myopathy, or muscular dystrophy, and also need ambulatory assistance or walking aids and meet the following conditions.

a) a weight within 40～100kg
b) a height of approximately 150～190cm, and body sizes like upper and lower leg length and hip width that fit the device.

[*1] News release for designation as a medical device for orphan diseases:
http://www.cyberdyne.jp/english/company/PressReleases_detail.html?id=1748
[*2] News release for submission of application for approval as a new medical device:
http://www.cyberdyne.jp/english/company/PressReleases_detail.html?id=2766
[*3] News release for consent by the Pharmaceutical Affairs and Food Sanitation Council (Medical Equipment and External Diagnosis Subcommittee):
http://www.cyberdyne.jp/english/company/PressReleases_detail.html?id=3698
[*4] News release for expanding target diseases in clinical trials:
http://www.cyberdyne.jp/english/company/PressReleases_detail.html?id=1210

(Reference 1) Ministry of Health, Labour and Welfare's Press Release
http://www.mhlw.go.jp/stf/houdou/0000105014.html (Japanese only)

(Reference 2) For this approval, the results of clinical research implemented by the Cabinet Office's Funding Program for World-Leading Innovative R&D on Science and Technology (FIRST)*a in order to practically use HAL in society as a new medical device, were applied. Achievements like the reception of an ISO certification for HAL for Living Support based on the robot safety technologies researched and developed by the New Energy and Industrial Technology Development Organization (NEDO)'s Living Assistance Robot Practical Application Project*b were also considered. The physician-directed medical trials by the Ministry of Health, Labour and Welfare's Scientific Research Grant "Practical Research Project for Rare/Intractable Diseases"*c recognized the effects of significant functional improvement and confirmed the safety of the device*d.

*a http://www.first.ccr.tsukuba.ac.jp/english/

*b http://www.nedo.go.jp/activities/EP_00270.html (Japanese only)

*c http://www.nanbyou.or.jp/entry/3627#02 (Japanese only)

*d http://www.niigata-nh.go.jp/html/etc/pdf/CHIKEN_HAL_20150406.pdf (Japanese only)

Company Profile:

Company Name	CYBERDYNE Inc.
Headquarters	2-2-1, Gakuen-Minami, Tsukuba, Ibaraki Prefecture, 305-0818, Japan
Capital Stock	JPY 16.511 Billion
Founded	June 24th, 2004
Business	Robot suit development, manufacture, sales
Stock Code	7779

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