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HAL Lower Limb Type obtained medical device approval for Indonesia ~Approved for wide range of diseases in the 4th most populated nation~

CYBERDYNE Inc. [Tsukuba, Ibaraki, CEO: Yoshiyuki Sankai (the “Company”)] obtained a medical device approval to manufacture and sell HAL for Medical Use Lower Limb Type, a device designed to improve the physical function of the wearer, from the Ministry of Health Republic of Indonesia (Kementerian Kesehatan Republik Indonesia), to be referred to as the “Ministry of Health”. Alike the approval that the Company obtained in Europe, Saudi Arabia, Malaysia and Thailand, the approval that the Company obtained on this occasion allows HAL to be used on a wide variety of diseases such as cerebrovascular disorder, spinal cord injury and Neuromuscular disease and etc. Following the approval, the Company can now offer Cybernics Treatment through its Medical HAL to Indonesia, which is known to be the 4th most populated nation in the world.



Cybernics Treatment with Medical HAL at Neuro Robotics Rehabilitation and Cybernics Centre
(within SOCSO Tun Razak Rehabilitation Centre, Melaka, Malaysia)

The Company started offering Cybernics Treatment with Medical HAL in October 2018 in Malaysia as the first nation in the Asia Pacific after Japan. Since then, the Company has been in communication with the governments, medical institutions and potential distributors in the Asia Pacific to prepare the installation of HAL. The Company regards Indonesia as one of the important medical device markets in the Asia Pacific, with the nation holding the largest number of populations in the region (4th in the world).



After the presentation in Indonesia

Left: CEO of Pusat Rehabilitasi PERKESO Sdn.
Bhd: Dr. Hafez bin Hussain



Reception at the seminar event hosted by BPJS

To install Medical HAL in Indonesia, the Company coordinated with the partner in Malaysia, PUSAT REHABILITASI PERKESO SDN. BHD (Kuala Lumpur, Malaysia, CEO: Dr. Hafez Bin Hussain) on the application for medical device approval, promotion of the technology towards medical facilities and public insurers. In an event hosted by Badan Penyelenggara Jaminan Sosial Ketenagakerjaan ("BPJS Ketenagakerjaan"), a labor and social security agency responsible for industrial compensation, death insurance, pension and old-age security, Dr Hafez gave a presentation on HAL and demonstrated the HAL applications to participants from BPJS, medical institutions and engineers.

As a result, the Company succeeded in receiving approval for its Medical HAL for treating cerebrovascular disorder, spinal cord injury and 8 types of slowly progressive rare neuromuscular disease from the Ministry of Health. Following this approval, the Company now proceeds to obtain medical approvals for HAL Single Joint Type and HAL Lumbar Type.

Furthermore, through the coordinated effort with PERKESO, the Company have signed a contract with one of the largest public hospitals in Indonesia on the installation of Medical HAL and have also completed the training course, for the staff to operate the devices. However, due to the large-scale social restriction that has been initiated as a countermeasure to the spreading of COVID-19, the delay in shipment of the product is expected to be unavoidable. The Company will keep a close watch on the effects of the COVID-19 pandemic and work to deliver each product as soon as possible.

The Company seeks to offer Cybernics Treatment, an innovative medical technology originated in Japan, to Indonesia with the aim of realizing a healthy and longevity society in which all people can enjoy healthy and prosperous lives.



A testee in demonstration explaining to others about his experience



Members related to BPJS, medical institutions and engineers who gathered to BPJS hosted seminar

Link

HAL Lower Limb Type obtained medical device approval from the Thai FDA

https://www.cyberdyne.jp/wp uploads/2020/04/20200413_PR_ENG.pdf

HAL Lower Limb Type obtained medical device approval from the Malaysian MDA

https://www.cyberdyne.jp/wp uploads/2019/10/20191015_PR_MDAML_ENG.pdf

“Neuro-Robotics Rehabilitation and Cybernics Center” established in Malaysia

https://www.cyberdyne.jp/wp uploads/2019/05/20190516_PR_ENG.pdf

Start of Cybernics Treatment in Asia Pacific region

https://www.cyberdyne.jp/wp uploads/2018/10/181016_NEWS_APAC_ENG.pdf

CYBERDYNE Inc.

URL	https://www.cyberdyne.jp/english/
Founded	June 2004
Share capital	26.778 billion Japanese yen (as of March 31, 2020 : non-consolidated, Japanese GAAP)
CEO	President and CEO Yoshiyuki Sankai
Address	2-2-1 Gakuen-minami, Tsukuba, Ibaraki, Japan

The Group’s business is to realize “Society 5.0/5.1”, a future society based on the idea of Techno-Peer-Support where human and technology live together and support each other. This goal is attained through revolutionary changes in industry and society, and The Group seeks to utilize “Cybernics Technology” (fusion and combination of systems of human, robot and information) that handles “human” + Cyberspace” + “Physical space”, to create a “Cybernics Industry” for this transition following the breakthroughs of the Robotics Industry and IT Industry.