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Company:	CYBERDYNE, INC.
Name of Representative:	Yoshiyuki Sankai, President and CEO
Code:	7779 (Mothers Section of the Tokyo Stock Exchange)
Contact:	Shinji Uga, Director and CFO (Tel. +81-29-869-9981)

HAL Single Joint Type obtained conformity certification as a medical device for EU ~Expansion of Medical HAL Series and Global Development~

CYBERDYNE, INC. 【Tsukuba, Ibaraki, CEO: Yoshiyuki Sankai (the "Company")】, obtained conformity certification to the Medical Device Directive in the EU ("MDD") by TÜV Rheinland LGA Products GmbH, Köln, Germany, for its Wearable Cyborg HAL for Medical Use Single Joint Type.

The Company currently offers its HAL for Medical Use Lower Limb Type to Japan, U.S., Europe, Middle East and Asia, as the world's first Wearable Cyborg with an acknowledged therapeutic effect. This conformity certification will add HAL Single Joint Type to the Medical HAL Series, expanding body parts that could be treated and situation of treatment. It will allow more patient to access the treatment with HAL for Medical Use Single Joint Type. The Company will offer this device to hospitals in Europe and also process regulatory applications to obtain medical device clearance in countries located outside of the EU.

(Feature of Medical HAL Single Joint Type)

- a) Light weight and compact design
- b) Enables intensive and effective Cybernics Treatment on Elbow, Knee and Ankle Joints
- c) Enables Cybernics Treatment while the patient lies on bed, sits on chair or stands up, depending on the condition of each patients.
- d) Enables Cybernics Treatment from very early stages, in which the patients has to stay on the bed.

* Cybernics Treatment: Cybernics Treatment is described as "Functional Regenerative Medicine" realized by devices like Medical HAL that are developed using Cybernics Technology, and it is an innovative treatment technology that promotes the functional improvement/regeneration of the brain-nerve- musculoskeletal 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 loop of functional improvement and regeneration that is in sync with the motion intent of the brain while avoiding excessive burden on the brain-nervemuscle systems, thus effectively altering the functions of the brain, nerves and musculoskeletal systems. Clinicians can intervene by turning 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 brainnerve system and the musculoskeletal system.

(MDD Conformity Certification)



(Medical HAL Single Joint Type that can be attached on various joints)

