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Marketing clearance from U.S. FDA for Medical HAL expands to stroke and progressive neuromuscular disease
~ clinical safety and medical efficacy of Medical HAL are recognized ~

On October 2 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") that expands the target to treatment of stroke and progressive neuro muscular disease[*1] in addition to spinal cord injury that was already cleared by the U.S. FDA.

The FDA clearance on October 2, 2020 recognizes Medical HAL's indication for use and its medical effect such as "temporarily help improve ambulation upon completion of the HAL gait training intervention" (not to enable individuals to perform ambulatory functions while it is worn) for wider range of diseases.

Important points of U.S. FDA clearance towards Medical HAL on October 2, 2020

1. Target diseases of Medical HAL expanded to "stroke" and "progressive neuromuscular disease"
- ① Paralysis due to stroke
- ② Paralysis due to progressive neuromuscular disease
  *****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

2. Significant treatment effect was acknowledged
- ① Stroke: Showed significant additional improvements for patients who no longer felt improvement in conventional rehabilitation.
- ② Progressive neuromuscular disease: Helped patients maintain their physical function above the baseline level before starting treatment for over 1.5 years without overusing or excessively burdening the muscles when used for patients in this population.

3. "Single-leg model" was also cleared
This allows wider choices of treatment, such as utilizing the double-leg model for paraplegic patients and either single-leg model or double-leg model for hemiplegic patients.