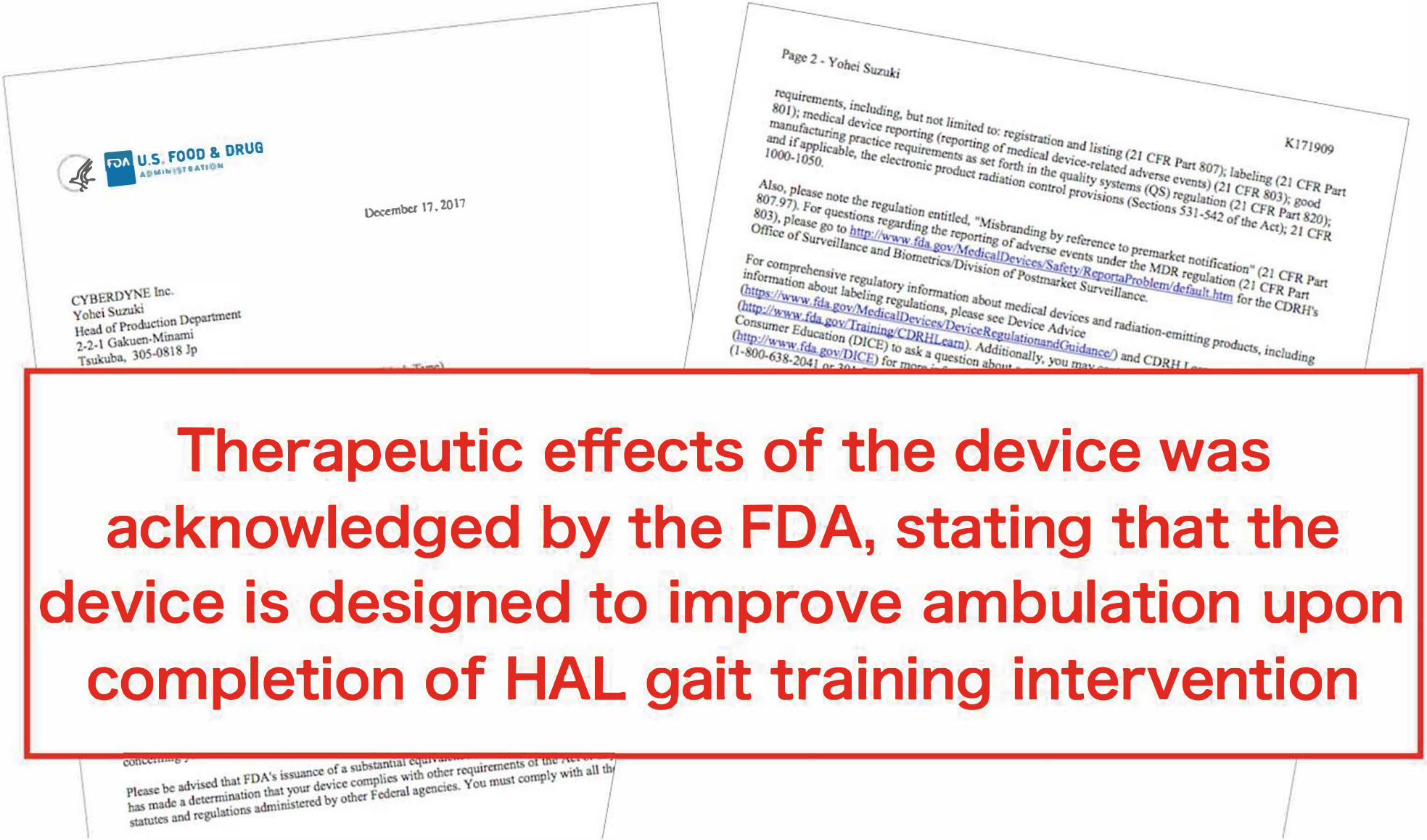
Medical HAL
Obtained marketing clearance from U.S. FDA
(2017/12/17)



Therapeutic effects of the device was acknowledged by the FDA, stating that the device is designed to improve ambulation upon completion of HAL gait training intervention

Medical HAL became the only medical device that is classified under the combination of these two categories,

- Neurological Devices §21 CFR 882.5050
- Physical Medicine Devices §21 CFR 890.3480

FDA also changed the definition of §21 CFR 890.3480!

FDA Product Classification 21 CFR 890.3480 **2017/12/11 (Before marketing approval)**

Definition	A powered exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation.
Physical State	The device is a wearable exoskeleton device that allows the user to enable ambulation over the course of the day. The control of the device is achieved through a wrist-worn user-operated wireless communicator, tilt sensor and specific body movements
Technical Method	The movement of the swing leg is controlled by a seat of gears and DC motors at the knee and hip joints. Minimizing energy expenditure with gait approximation is critical for maximizing battery life between charges.
Target Area	The device legs consist of left and right interconnect hip and knee segments. Multiple attachment straps are mounted along the length of each leg. The pelvic band support provides a structure to join the two legs together and the pelvic strap helps hold the user firmly in the system. A tilt sensor is mounted on the left side of the pelvic band. The ankle/foot bed holds the calves of the user to the system.
Regulation Medical Specialty	Physical Medicine
Review Panel	Neurology
Product Code	PHL
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medic Physical Medicine and Rehabilitation Device
Submission Type	510(k)
Regulation Number	890.3480
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

2017/12/18 (After marketing approval)

Definition	A powered exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened lower extremity limb(s) for medical purposes.
Physical State	The device is comprised of external, powered, orthotic components that rely on controllers and/or sensors.
Technical Method	The device facilitates movement of one or multiple lower extremity joints (e.g. hip, knee, ankle).
Target Area	The device is intended to be used on the lower extremity. It may be used unilaterally, bilaterally, on a single joint, or on multiple joints.
Regulation Medical Specialty	Physical Medicine
Review Panel	Neurology
Product Code	PHL
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices (DNPMD) Physical Medicine and Rehabilitation Devices Branch (PMDB)
Submission Type	510(k)

Major difference between HAL and other devices

	HAL for Medical Use	Other Devices
Classification Name	Powered Lower Extremity Exoskeleton (primary) **Biofeedback Device**	Powered Lower Extremity Exoskeleton
Regulation Number	Physical Medicine Devices 21 CFR 890.3480 (primary) **Neurological Devices** **21 CFR 882.5050**	Physical Medicine Devices 21 CFR 890.3480
Product Code	PHL (primary) **HCC**	PHL
Indications for Use	**Improvement ambulation** upon completion of HAL gait training intervention	Perform ambulation while the device is worn
level of spinal cord injury	C4~L5	T4~L5 (ReWalk), T4~L5 (Indigo), C7~L5 (Ekso) [Ekso can be used for stroke]
Method of Control	Mainly controlled by **Bioelectrical signals** at knee and hip extensor and flex muscles	Remote control worn on write to change modes; postal cues for stepping *Feature of predicate devices and other devices with a product code of PHL
Clinical Studies	The clinical result suggest **both statistically and clinically significant improvement** without wearing the HAL device	Safe to use and enables the user to perform ambulatory functions better while the device is worn

Business Development in USA

Joint venture established with one of the largest rehabilitation hospital group, "Brooks Rehabilitation" on establishment of a center for Cybernic Treatment with HAL (2018/02)

BROOKS®
CYBERNIC
TREATMENT CENTER

- 45,000 patients p.a.
- one of the largest inpatient rehab hospitals in USA
- 32 outpatient clinics
- clinical research centers for stroke, spinal cord injury, etc.

left: Yoshiyuki Sankai, President & CEO, CYBERDYNE INC. right: Michael Spigel, President & COO, Brooks Rehabilitation