



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 344232 Vigor Technologies Pty Ltd - HAL - Neuro-controlled ambulation exoskeleton

**ARTG entry for** Medical Device Included Class IIa  
**Sponsor** Vigor Technologies Pty Ltd  
**Postal Address** iAccelerate (239) Innovation Campus Squires Way, North Wollongong, NSW, 2500  
Australia  
**ARTG Start Date** 23/09/2020  
**Product Category** Medical Device Class IIa  
**Status** Active  
**Approval Area** Medical Devices

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

Name	Address
Cyberdyne Inc	2-2-1 Gakuen Minami Tsukuba, Ibaraki, 305-0818 Japan

### Products

#### 1 . HAL - Neuro-controlled ambulation exoskeleton

Product Type	Single Device Product	Effective Date	23/09/2020
--------------	-----------------------	----------------	------------

**GMDN** 63288 Neuro-controlled ambulation exoskeleton

**Intended Purpose** HAL is a medical device that achieves functional improvement of the neuromuscular system for voluntary movement, by feeding back sensory signals related to the movement of the lower limbs that is realised by the device's motorised assistance, controlled in real time by voluntary bio-electrical signals and robotic autonomous control. By enabling their voluntary movement using actuators at the relevant joints during treatment sessions, this medical device synchronises the patient's intent to move with actual movement and feedback signals, thereby improving neuromuscular function of the paralysed limbs of patients with brain-neuromuscular diseases and orthopedic conditions. Treatment must be provided indoors in medical facilities under medical supervision in accordance with the patient assessment and certification program for medical personnel. It is not intended for strenuous activity such as running or jumping, and must be used in combination with comprehensive fall prevention systems when worn to perform movements that include standing-up and walking.

### Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary