

2021/9/2

Company: CYBERDYNE Inc.

Name of Yoshiyuki Sankai, Representative: President and CEO

7779 (Mothers Section of the Tokyo

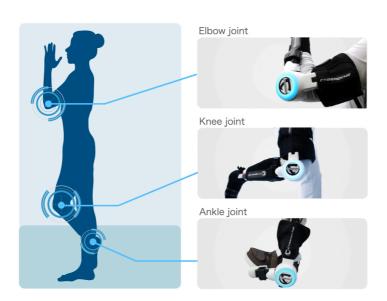
Stock Exchange)

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## [News] Medical HAL Single Joint Type receives medical device approval from Australian regulator

CYBERDYNE Inc. (Tsukuba, Ibaraki, Japan, President & CEO: Yoshiyuki Sankai) announced today that its application for a medical device marketing license for Medical HAL Single Joint Type, a Wearable Cyborg that improves physical functions, has been approved by the Australian Therapeutic Goods Administration, Department of Health (TGA). TGA registered the summary of the product on the Australian Register of Therapeutic Goods (ARTG)\*1. The approved target diseases cover cerebrovascular disorders (stroke) and treatment after orthopedic surgery, as in the EU.



Medical HAL Single Joint Type

The Company has obtained medical device approvals in Japan, the U.S., and the EU for Medical HAL Single Joint Type. In the Asia-Pacific region (APAC), the approval of the medical device in Australia follows those in Malaysia and Thailand. In collaboration with our local partners, we will deploy Cybernics Treatment, an innovative medical technology originating from Japan, in Australia and contribute to realizing a society of health and longevity where all people can enjoy healthy and affluent lives.

\*1 After receiving evaluation for safety and functionality, a company must register their medical device sold in Australia in the Australian Register of Therapeutic Goods (ARTG) managed by the TGA.

## Reference)

Public summary of Medical HAL Single Joint Type registered on ARTG <a href="https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=46C122">https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=46C122</a> <a href="https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=46C122">https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=46C122</a> <a href="https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=46C122">https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=46C122</a> <a href="https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=46C122">https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=46C122</a> <a href="https://www.ebs.tga.gov.au/servlet/xmlmillr6">https://www.ebs.tga.gov.au/servlet/xmlmillr6</a>?dbid=ebs/PublicHTML/pdfStore.nsf&docid=46C122</a> <a href="https://www.ebs.tga.gov.au/servlet/xmlmillr6">https://www.ebs.tga.gov.au/servlet/xmlmillr6</a>?dbid=ebs/publ

August 30, 2021

CYBERDYNE listed Medical HAL Single Joint Type to U.S. FDA as Class I Medical Device https://www.cyberdyne.jp/english/company/PressReleases\_detail.html?id=11345

July 13, 2020

HAL Single Joint Type obtained certification as a medical device for Japan, applied for insurance coverage

https://www.cyberdyne.jp/wp uploads/2020/07/20200713 PR eng.pdf

October 8, 2019

HAL Single Joint Type obtained conformity certification as a medical device for EU https://www.cyberdyne.jp/wp\_uploads/2019/10/20191008\_PR\_Single-Joint\_ENG.pdf