FDA 510(k) Premarket Notification

K171909 HAL for Medical Use (Lower Limb Type)

CLEARED

Dec 17, 2017
174 days to decision

K171909 · Product code: **PHL** · Neurology
Source: https://www.510kdatabase.net/k171909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	Jun 26, 2017
Decision date	Dec 17, 2017
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cyberdyne, Inc.**
Location	Tsukuba, JP
Contact	Yohei Suzuki
510(k) history	3 submissions · 3 cleared · 2017-2024