FDA 510(k) Premarket Notification

K182768 TMS-Cobot TS MV

CLEARED

Feb 17, 2019
142 days to decision

K182768 · Product code: **QFF** · Neurology
Source: https://www.510kdatabase.net/k182768/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electromechanical Arm For A Transcranial Magnetic Stimulation System (QFF)
Date received	Sep 28, 2018
Decision date	Feb 17, 2019
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Axilum Robotics**
Location	Strasbourg, FR
Contact	Romuald Ginhoux
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov