FDA 510(k) Premarket Notification

K221215 e-motion M25

CLEARED

May 24, 2022
27 days to decision

K221215 · Product code: **ITI** · Physical Medicine
Source: https://www.510kdatabase.net/k221215/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wheelchair, Powered (ITI)
Date received	Apr 27, 2022
Decision date	May 24, 2022
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Alber GmbH**
Location	Albstadt, DE
Contact	Christoph Hauschel
510(k) history	5 submissions · 5 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	**Beo Medconsulting Berlin GmbH**
Contact	Michael Vent

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