FDA 510(k) Premarket Notification

K203761 ParaMotion

CLEARED

Jan 21, 2022
394 days to decision

K203761 · Product code: **IPL** · Physical Medicine
Source: https://www.510kdatabase.net/k203761/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Standup (IPL)
Date received	Dec 23, 2020
Decision date	Jan 21, 2022
Days to decision	394 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Powerbasetec GmbH**
Location	Bodensee, DE
Contact	Niclas Nachtwey
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Qip GmbH**
Contact	Juliane Dinter

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