

K203761 ParaMotionJan 21, 2022
394 days to decisionK203761 · Product code: **IPL** · Physical MedicineSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203761/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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