

K212503 HP458E Electrically Powered WheelchairJan 18, 2022
162 days to decisionK212503 · Product code: ITI · Physical Medicine
Source: <https://www.510kdatabase.net/k212503/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Aug 9, 2021
Decision date	Jan 18, 2022
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kunshan Hi-Fortune Health Products Co., Ltd.
Location	Kunshan, CN
Contact	Jianjiang Fan
510(k) history	9 submissions · 9 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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

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