

K201855 Electrically Powered Wheelchair -Model HP358ESep 28, 2021
449 days to decision

K201855 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k201855/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Jul 6, 2020
Decision date	Sep 28, 2021
Days to decision	449 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201855/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026