

**K211647 HP358EA Electrically Powered Wheelchair**Jan 4, 2022  
221 days to decisionK211647 · Product code: ITI · Physical Medicine  
Source: <https://www.510kdatabase.net/k211647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	May 28, 2021
Decision date	Jan 4, 2022
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211647/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026