

K220227 Auto Folding Scooter, S21FOct 12, 2022
258 days to decisionK220227 · Product code: **INI** · Physical MedicineSource: <https://www.510kdatabase.net/k220227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Jan 27, 2022
Decision date	Oct 12, 2022
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Heartway Medical Products Co., Ltd.
Location	Hsin-Chu City, TW
Contact	Ke-Min Jen
510(k) history	23 submissions · 23 cleared · 1997-2022

REGULATORY CONSULTANT

Consulting firm	Roc Chinese-European Industrial Research Society
Contact	Ke-Min Jen

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/k220227/> 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 14, 2026