

K132855 HEARTWAY POWER MOBILITY SCOOTERAug 29, 2014
351 days to decisionK132855 · Product code: **INI** · Physical MedicineSource: <https://www.510kdatabase.net/k132855/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Vehicle, Motorized 3-wheeled (INI) |
| Date received | Sep 12, 2013 |
| Decision date | Aug 29, 2014 |
| Days to decision | 351 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Heartway Medical Products Co., Ltd. |
| Location | Hsin-Chu City, TW |
| Contact | JEN KE-MIN |
| 510(k) history | 23 submissions · 23 cleared · 1997-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132855/> 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 27, 2026