

K243440 Electric Wheelchair (HC820N)Dec 19, 2024
43 days to decision

K243440 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k243440/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wheelchair, Powered (ITI) |
| Date received | Nov 6, 2024 |
| Decision date | Dec 19, 2024 |
| Days to decision | 43 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | Yongkang Hengyi Vehicle Co., Ltd. |
| Location | Yongkang, CN |
| Contact | Kathryn Zhu |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Shanghai SUNGO Management Consulting Co., Ltd. |
| Contact | Ariel Xiang |

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/k243440/> 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