

K190534 Manual Wheelchair SIVFH2A102May 29, 2019
86 days to decisionK190534 · Product code: **IOR** · Physical Medicine
Source: <https://www.510kdatabase.net/k190534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Mechanical (IOR)
Date received	Mar 4, 2019
Decision date	May 29, 2019
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Horizon Medical Science & Technology Co., Ltd.
Location	Situ Town, Danyang City, CN
Contact	Cheng Gong
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Guangzhou Junyi Information Technology Co., Ltd.
Contact	Jinghua Zhou

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/k190534/> 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 June 28, 2026