

K252517 Manual Wheelchair (SYIV100A008)Oct 3, 2025
53 days to decisionK252517 · Product code: **IOR** · Physical Medicine
Source: <https://www.510kdatabase.net/k252517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Mechanical (IOR)
Date received	Aug 11, 2025
Decision date	Oct 3, 2025
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Ningbo Shenyu Medical Equipment Co.,Ltd
Location	Yuyao, CN
Contact	Song Zhenyong
510(k) history	4 submissions · 4 cleared · 2021-2026

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/k252517/> 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 13, 2026