FDA 510(k) Premarket Notification

CLEARED

K254141 Manual Wheelchair (DY01903(2))

May 21, 2026
150 days to decision

K254141 · Product code: **IOR** · Physical Medicine
Source: https://www.510kdatabase.net/k254141/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Mechanical (IOR)
Date received	Dec 22, 2025
Decision date	May 21, 2026
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guangdong Dayang Medical Technology Co., Ltd.**
Location	Foshan, CN
Contact	Xueqiong Zhang
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Shanghai SUNGO Management Consulting Co., Ltd.**
Contact	Andrew Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov