FDA 510(k) Premarket Notification

CLEARED

K231750 MA012 Aluminum wheelchair, MS019 steel wheelchair

Aug 15, 2023
61 days to decision

K231750 · Product code: **IOR** · Physical Medicine
Source: https://www.510kdatabase.net/k231750/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Mechanical (IOR)
Date received	Jun 15, 2023
Decision date	Aug 15, 2023
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sichuan Ast Medical Equipment Co., Ltd.**
Location	Luzhou City, CN
Contact	Mae Tse
510(k) history	3 submissions · 3 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	**Shanghai Sungo Management Consulting Company Limited.**
Contact	Ivy Wang

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