

K242358 Powered wheelchair (mobility robot) (M4, M4U)Apr 3, 2025
238 days to decision

K242358 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k242358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Aug 8, 2024
Decision date	Apr 3, 2025
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Xsto Co., Ltd.
Location	Zhongshan, CN
Contact	Jingbu Xu
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Share Info (Guangzhou) Medical Consultant , Ltd.
Contact	Cassie Lee

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

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