

K254012 Electric Wheelchair (E201)Mar 24, 2026
99 days to decision

K254012 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k254012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Dec 15, 2025
Decision date	Mar 24, 2026
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanjing CareMoving Rehabilitation Equipment Co.,Ltd
Location	Nanjing, CN
Contact	James Gu
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Eva Li

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254012/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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