

K253806 Power Wheelchair (N5919 series)Apr 20, 2026
143 days to decisionK253806 · Product code: ITI · Physical Medicine
Source: <https://www.510kdatabase.net/k253806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wheelchair, Powered (ITI)
Date received	Nov 28, 2025
Decision date	Apr 20, 2026
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Zhejiang Innuovo Rehabilitation Devices Co.,Ltd
Location	Dongyang, CN
Contact	Yolanda Ge
510(k) history	16 submissions · 16 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Ivy Wang

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

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