

**K251565 Wheelchair (N817)**Oct 6, 2025  
137 days to decision

K251565 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k251565/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	May 22, 2025
Decision date	Oct 6, 2025
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Topwe Tools Manufacturing Co.,Ltd</b>
Location	Yongkang, CN
Contact	Liang Wang
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Ariel Xiang

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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