

K250729 Power Wheelchair (MOB1107)Jul 2, 2025
113 days to decisionK250729 · Product code: ITI · Physical Medicine
Source: <https://www.510kdatabase.net/k250729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Mar 11, 2025
Decision date	Jul 2, 2025
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vive Health, LLC
Location	Naples, FL, US
Contact	Guy Savioli
Website	https://www.vivehealth.com
510(k) history	2 submissions · 2 cleared · 2025-2025

Vive Health, LLC is an online medical equipment and supplies retailer offering a broad range of home health devices and mobility aids. The company operates with a manufacturing facility in Naples, US. Vive Health has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's cleared devices span cardiovascular and physical medicine categories, with clearances issued in 2025. This recent regulatory activity demonstrates active engagement in the FDA 510(k) clearance process. The company's product portfolio includes power wheel...

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Kiwi Xu

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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Device record: <https://www.510kdatabase.net/k250729/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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