

**K240105 Navigator (FMNVG15)**Aug 29, 2024  
226 days to decisionK240105 · Product code: ITI · Physical Medicine  
Source: <https://www.510kdatabase.net/k240105/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Jan 16, 2024
Decision date	Aug 29, 2024
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Navigator XL (FMNVX06)

**APPLICANT**

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Company	<b>Forcemech International, LLC</b>
Location	Pearland, TX, US
Contact	David Ou
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Jarvis Wu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240105/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026