FDA 510(k) Premarket Notification

# K240105 Navigator (FMNVG15)

**CLEARED**

Aug 29, 2024
226 days to decision

K240105 · 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

| | |
|---|---|
| Company | **Forcemech International, LLC** |
| Location | Pearland, TX, US |
| Contact | David Ou |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Shanghai SUNGO Management Consulting Co., Ltd.** |
| Contact | Jarvis Wu |

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