FDA 510(k) Premarket Notification

CLEARED

K261410 Navbit MARQ (PRD-001-SUP (Supine Registration Kit), PRD-001-LAT (Lateral Registration Kit))

Jul 30, 2026
91 days to decision

K261410 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k261410/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 30, 2026
Decision date	Jul 30, 2026
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Suite 201, National Innovation Centre**
Location	Nsw, AU
Contact	David Thomson
510(k) history	1 submissions · 1 cleared · 2026-2026