FDA 510(k) Premarket Notification

CLEARED

K260011 Foundation Surgical Navigated Lateral Disc Prep Instruments

Apr 16, 2026
104 days to decision

K260011 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k260011/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 2, 2026
Decision date	Apr 16, 2026
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Foundation Surgical Group, Inc.**
Location	Scottsdale, AZ, US
Contact	Asher Breverman
510(k) history	3 submissions · 3 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**Applied Technical Services (Empirical Technologies)**
Contact	Hannah Taggart

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