

K243326 Dynamis Robotic Surgical SystemApr 23, 2025
181 days to decisionK243326 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k243326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Oct 24, 2024
Decision date	Apr 23, 2025
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	LEM Surgical AG
Location	Bern, CH
Contact	Yossi Bar
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Alexia Haralambous

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

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