

K232140 OTS HipMar 11, 2024
237 days to decisionK232140 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k232140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 18, 2023
Decision date	Mar 11, 2024
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ortoma AB
Location	Goteborg, SE
Contact	Linus Byström
510(k) history	3 submissions · 3 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells, LLC
Contact	John Smith

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

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