

K250086 OTS HipMay 16, 2025
123 days to decisionK250086 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k250086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 13, 2025
Decision date	May 16, 2025
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ortoma AB
Location	Goteborg, SE
Contact	Anders Hahn
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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