FDA 510(k) Premarket Notification

K232140 OTS Hip

CLEARED

Mar 11, 2024
237 days to decision

K232140 · 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