

K261852 OTS Hip

Jul 1, 2026
28 days to decision

K261852 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k261852/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 3, 2026
Decision date	Jul 1, 2026
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortoma AB
Location	Goteborg, SE
Contact	Fredrik Strömberg
510(k) history	4 submissions · 4 cleared · 2018-2026