

**K233542 Ortho Guidance Precision Knee Software**Mar 14, 2024  
132 days to decisionK233542 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k233542/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 3, 2023
Decision date	Mar 14, 2024
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Ortho Guidance Express Knee Software; Ortho Guidance Versatile Hip Software; Q Guidance System

**APPLICANT**

---

Company	<b>Stryker Leibinger GmbH &amp; Co KG</b>
Location	Freiburg Im Breisgau, DE
Contact	Megan B Guilbault
510(k) history	21 submissions · 21 cleared · 2009-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233542/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026