

K252871 Spine Guidance 5.3 SoftwareFeb 6, 2026
149 days to decisionK252871 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k252871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 10, 2025
Decision date	Feb 6, 2026
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Q Interbody Instruments; Elite Q Attachments; Elite Cutting Accessories

APPLICANT

Company	Stryker Leibinger GmbH & Co KG
Location	Freiburg Im Breisgau, DE
Contact	Andrea Wallen-Gerding
510(k) history	21 submissions · 21 cleared · 2009-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252871/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026