

**K240662 Spine Guidance Software (version 5.0)**Jun 6, 2024  
90 days to decisionK240662 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k240662/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Mar 8, 2024
Decision date	Jun 6, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Xia 3/ Serrato Q Instruments; Everest Q Instruments; Mesa 2 Q Instruments; Q Pedicle Preparation Instruments; Q S2AI Drills; Q Handles; Consolidated Operating Room Equipment (CORE) 2 Console; Electric System 6 Dual Trigger Rotary Handpiece

**APPLICANT**

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

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