

K253623 Spine Guidance 5.4 SoftwareFeb 19, 2026
93 days to decisionK253623 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k253623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 18, 2025
Decision date	Feb 19, 2026
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Spine Guidance 5.4 Upgrade; Spine Guidance 5.4 Update; Spine Guidance 5.4 Software Enable; Spine Guidance 5.4 Sales Demo; Q Drill Tracker; NavLock Adapter; Elite Q Attacments; Elite Cutting Accessories; Maestro Air Motor

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

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