

K241517 Q Guidance SystemAug 27, 2024
90 days to decisionK241517 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k241517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 29, 2024
Decision date	Aug 27, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Mako Spine System;

APPLICANT

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

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