

K203205 Navigated Spine InstrumentsMar 23, 2021
144 days to decisionK203205 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k203205/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Oct 30, 2020
Decision date	Mar 23, 2021
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Spine
Location	Allendale, NJ, US
Contact	Megan Callanan
510(k) history	74 submissions · 73 cleared · 2004-2026

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