

K191854 Premia Spine XL InstrumentsOct 8, 2019
90 days to decisionK191854 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k191854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 10, 2019
Decision date	Oct 8, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Premia Spine, Ltd.
Location	Ramat Poleg, IL
Contact	Ron Sacher
510(k) history	6 submissions · 6 cleared · 2015-2023

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