

K162921 Navigated Instrument SystemMar 13, 2017
146 days to decisionK162921 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k162921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Oct 18, 2016
Decision date	Mar 13, 2017
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix, Inc.
Location	Mckinney, TX, US
Contact	JACKI KOCH
510(k) history	57 submissions · 57 cleared · 1996-2024

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