

K192336 Navigated Anterolateral Disc Prep InstrumentsNov 22, 2019
86 days to decisionK192336 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k192336/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 28, 2019
Decision date	Nov 22, 2019
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	Parwinder Singh
510(k) history	170 submissions · 159 cleared · 2000-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192336/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026