

**K163581 Navigated ELEVATE Inserter, Navigated Disc Prep Instruments**Apr 14, 2017  
115 days to decisionK163581 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k163581/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 20, 2016
Decision date	Apr 14, 2017
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek USA, Inc.</b>
Location	Memphis, TN, US
Contact	LAVEEDA LEFLORE
510(k) history	170 submissions · 159 cleared · 2000-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163581/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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