

**K181111 Navigated INFINITY Instruments**May 17, 2018  
20 days to decisionK181111 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k181111/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 27, 2018
Decision date	May 17, 2018
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181111/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026