

K162680 SOVEREIGN® Spinal SystemDec 14, 2016
79 days to decisionK162680 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k162680/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Sep 26, 2016
Decision date	Dec 14, 2016
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162680/> 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