

K172328 SOVEREIGN™ Spinal SystemNov 2, 2017
92 days to decisionK172328 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k172328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Aug 2, 2017
Decision date	Nov 2, 2017
Days to decision	92 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

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