

**K162212 DIVERGENCE-L ANTERIOR/OBLIQUE LUMBAR
FUSION SYSTEM**May 19, 2017
284 days to decisionK162212 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k162212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 8, 2016
Decision date	May 19, 2017
Days to decision	284 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162212/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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