FDA 510(k) Premarket Notification

K162212 DIVERGENCE-L ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM

CLEARED

May 19, 2017
284 days to decision

K162212 · 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