FDA 510(k) Premarket Notification

K160418 PERIMETER Interbody Fusion Device

CLEARED

Mar 7, 2016
20 days to decision

K160418 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k160418/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 16, 2016
Decision date	Mar 7, 2016
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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