FDA 510(k) Premarket Notification

K131669 PERIMETER INTERBODY FUSION DEVICE

CLEARED

Nov 1, 2013
147 days to decision

K131669 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k131669/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 7, 2013
Decision date	Nov 1, 2013
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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