FDA 510(k) Premarket Notification

K171312 FortiCore®

CLEARED

Jan 22, 2018
263 days to decision

K171312 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k171312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 4, 2017
Decision date	Jan 22, 2018
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nanovis, LLC**
Location	San Diego, CA, US
Contact	Matthew Hedrick
510(k) history	10 submissions · 10 cleared · 2011-2024