FDA 510(k) Premarket Notification

K162693 VertebraLINK Fusion Platform

CLEARED

Mar 29, 2017
183 days to decision

K162693 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k162693/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 27, 2016
Decision date	Mar 29, 2017
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Facetlink Dba Linkspine**
Location	Rockaway, NJ, US
Contact	MASSIMO CALAFIORE
510(k) history	2 submissions · 2 cleared · 2016-2017