FDA 510(k) Premarket Notification

K171630 LumFuse-TP

CLEARED

Jul 25, 2017
53 days to decision

K171630 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k171630/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 2, 2017
Decision date	Jul 25, 2017
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Precifit Medical, Ltd.**
Location	Morrisville, NC, US
Contact	ZhenYu (Eric) Wu
510(k) history	4 submissions · 4 cleared · 2017-2018