FDA 510(k) Premarket Notification

K173189 Lumfuse TP

CLEARED

Jun 8, 2018
249 days to decision

K173189 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k173189/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 2, 2017
Decision date	Jun 8, 2018
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k173189/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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