FDA 510(k) Premarket Notification

K172568 Cervage

CLEARED

May 4, 2018
252 days to decision

K172568 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k172568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 25, 2017
Decision date	May 4, 2018
Days to decision	252 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