FDA 510(k) Premarket Notification

K172484 A-CIFT SoloFuse

CLEARED

May 8, 2018
264 days to decision

K172484 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k172484/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Aug 17, 2017
Decision date	May 8, 2018
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spinefrontier, Inc.**
Location	Beverly, MA, US
Contact	Vito Lore
510(k) history	24 submissions · 24 cleared · 2007-2020

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Meredith L. May

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov