FDA 510(k) Premarket Notification

K182477 Cervical Spacer

CLEARED

Jan 28, 2019
140 days to decision

K182477 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k182477/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 10, 2018
Decision date	Jan 28, 2019
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Additive Implants, LLC**
Location	Pheonix, AZ, US
Contact	Jeff Horn
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting**
Contact	Karen E. Warden

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