FDA 510(k) Premarket Notification

CLEARED

K162351 SeaSpine® Vu a•POD™ Prime NanoMetalene® Intervertebral Body Fusion Device

Dec 1, 2016
100 days to decision

K162351 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k162351/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Aug 23, 2016
Decision date	Dec 1, 2016
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**SeaSpine Orthopedics Corporation**
Location	Carlsbad, CA, US
Contact	Gina Flores
510(k) history	66 submissions · 66 cleared · 2016-2025