FDA 510(k) Premarket Notification

K170569 SeaSpine Shoreline ACS - Anterior Cervical Standalone System

CLEARED

Jun 15, 2017
108 days to decision

K170569 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k170569/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Feb 27, 2017
Decision date	Jun 15, 2017
Days to decision	108 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