K190655 SeaSpine® Shoreline™ ACS- Anterior Cervical Standalone System

CLEARED

Apr 29, 2019
46 days to decision

K190655 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k190655/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Mar 14, 2019
Decision date	Apr 29, 2019
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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