

K201646 Shoreline ACS (Anterior Cervical System)Sep 14, 2020
89 days to decisionK201646 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k201646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jun 17, 2020
Decision date	Sep 14, 2020
Days to decision	89 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

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