

K161081 SeaSpine Shoreline ACS - Anterior Cervical Standalone SystemSep 14, 2016
149 days to decisionK161081 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k161081/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Apr 18, 2016
Decision date	Sep 14, 2016
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161081/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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