

K213359 SeaSpine WaveForm, C Interbody SystemDec 9, 2021
58 days to decisionK213359 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k213359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Oct 12, 2021
Decision date	Dec 9, 2021
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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