

K210583 SeaSpine WaveForm™ A Interbody SystemJun 2, 2021
96 days to decisionK210583 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k210583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 26, 2021
Decision date	Jun 2, 2021
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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