

**K213420 WaveForm L System, WaveForm TO System, WaveForm TA System**

May 4, 2022  
196 days to decision

K213420 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k213420/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 20, 2021
Decision date	May 4, 2022
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k213420/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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