

K220902 Navagio Lumbar CageMay 27, 2022
60 days to decisionK220902 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k220902/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 28, 2022
Decision date	May 27, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kalitec Medical, LLC
Location	Orlando, FL, US
Contact	Scott Winn
510(k) history	2 submissions · 2 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	The OrthoMedix Group, Inc.
Contact	J. D. Webb

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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