

K193645 nva, nvp, and nvtJan 13, 2020
14 days to decisionK193645 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k193645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 30, 2019
Decision date	Jan 13, 2020
Days to decision	14 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nvision Biomedical Technologies, Inc.
Location	San Antonio, TX, US
Contact	Diana Langham
510(k) history	24 submissions · 24 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	Watershed Ideas Foundry
Contact	Jeffrey Brittan

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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