FDA 510(k) Premarket Notification

K193645 nva, nvp, and nvt

CLEARED

Jan 13, 2020
14 days to decision

K193645 · 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