FDA 510(k) Premarket Notification

K193370 Nexxt Matrixx System

CLEARED

Jan 21, 2020
47 days to decision

K193370 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k193370/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 5, 2019
Decision date	Jan 21, 2020
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nexxt Spine, LLC**
Location	Chesterland, OH, US
Contact	Andy Elsbury
510(k) history	22 submissions · 22 cleared · 2009-2023

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting**
Contact	Karen E Warden

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