FDA 510(k) Premarket Notification

K193211 Nano FortiFix® System

CLEARED

Mar 20, 2020
120 days to decision

K193211 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k193211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 21, 2019
Decision date	Mar 20, 2020
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nanovis Spine, LLC**
Location	Columbia City, IN, US
Contact	Matthew Hedrick
510(k) history	3 submissions · 3 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting, Inc.**
Contact	Karen E Warden

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