FDA 510(k) Premarket Notification

K220291 NEXXT SPINE NAVIGATION System

CLEARED

Mar 31, 2022
58 days to decision

K220291 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k220291/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 1, 2022
Decision date	Mar 31, 2022
Days to decision	58 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, Inc.**
Contact	Karen E Warden

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