FDA 510(k) Premarket Notification

K210539 CoreLink Midline Fixation System

CLEARED

Apr 15, 2021
50 days to decision

K210539 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k210539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 24, 2021
Decision date	Apr 15, 2021
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corelink, LLC**
Location	Round Rock, TX, US
Contact	Steven Mounts
510(k) history	35 submissions · 35 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Nathan Wright

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