FDA 510(k) Premarket Notification

K201568 Calvary Spine Pedicle Screw System

CLEARED

Nov 12, 2020
154 days to decision

K201568 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k201568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 11, 2020
Decision date	Nov 12, 2020
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Calvary Spine, LLC**
Location	Round Rock, TX, US
Contact	James Edwards
510(k) history	2 submissions · 2 cleared · 2008-2020

REGULATORY CONSULTANT

Consulting firm	**The OrthoMedix Group, Inc.**
Contact	J.D. Webb

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