

K201568 Calvary Spine Pedicle Screw SystemNov 12, 2020
154 days to decisionK201568 · 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](https://accessdata.fda.gov)

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