

K193472 OrthoCircle Spine Pedicle Screw SystemFeb 13, 2020
59 days to decisionK193472 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k193472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 16, 2019
Decision date	Feb 13, 2020
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthocircle Spine
Location	Savannah, GA, US
Contact	Jack Mathews
510(k) history	1 submissions · 1 cleared · 2020-2020

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

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