

K230974 NIDO™ Pedicle Screw SystemSep 15, 2023
163 days to decisionK230974 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k230974/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 5, 2023
Decision date	Sep 15, 2023
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kalitec Medical
Location	Orlando, FL, US
Contact	Keith Cannon
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	MCRA
Contact	Justin Eggleton

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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