

K192800 Streamline TL Spinal Fixation SystemJan 14, 2020
106 days to decisionK192800 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k192800/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 30, 2019
Decision date	Jan 14, 2020
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pioneer Surgical Technology, Inc. (Db a Rti Surgical, Inc.)
Location	Marquette, MI, US
Contact	Kurtis Hunsberger
510(k) history	15 submissions · 15 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
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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