

K191576 Mercury® Spinal System, Overwatch® Spinal SystemSep 16, 2019
94 days to decisionK191576 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k191576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 14, 2019
Decision date	Sep 16, 2019
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spinal Elements, Inc.
Location	Carlsbad, CA, US
Contact	Julie Lamothe
Website	https://www.spinalelements.com
510(k) history	48 submissions · 48 cleared · 2007-2026

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