

K180376 K2M Patient Specific RodsApr 5, 2018
52 days to decisionK180376 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k180376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 12, 2018
Decision date	Apr 5, 2018
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	K2m, Inc.
Location	Leesburg, VA, US
Contact	Nancy Giezen
510(k) history	100 submissions · 97 cleared · 2007-2026

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