

K210420 Goblin and Goblin LS Pedicle Screw SystemsApr 19, 2021
67 days to decisionK210420 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k210420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 11, 2021
Decision date	Apr 19, 2021
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medynus, Inc.
Location	Irvine, CA, US
Contact	David Shin
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Eerkie Corporation
Contact	Jeena Mathai

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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