

K220285 PINE Pedicle Screw SystemMay 19, 2022
107 days to decisionK220285 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k220285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 1, 2022
Decision date	May 19, 2022
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tdm Co., Ltd.
Location	Gwangju, KR
Contact	Choi Jung Wook
510(k) history	11 submissions · 11 cleared · 2018-2024

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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