

K231737 ANAX™ 5.5 Spinal SystemOct 26, 2023
134 days to decisionK231737 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k231737/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 14, 2023
Decision date	Oct 26, 2023
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innosys Co., Ltd.
Location	Uijeongbu-Si, KR
Contact	Hye-Kyung Lee
510(k) history	4 submissions · 4 cleared · 2023-2024

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