

K233960 INNOVERSE Spinal SystemFeb 6, 2024
53 days to decisionK233960 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k233960/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 15, 2023
Decision date	Feb 6, 2024
Days to decision	53 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233960/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026