

K222031 Spinal Inner Fixation SystemOct 28, 2022
109 days to decisionK222031 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k222031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 11, 2022
Decision date	Oct 28, 2022
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Geasure Medical Apparatus and Instruments Co., Ltd.
Location	Changzhou, CN
Contact	Jing Huang
510(k) history	4 submissions · 4 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Sinow Medical AS
Contact	Xiaoqing Xue

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222031/> 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 26, 2026