

K221745 Sterile Posterior Spinal Fixation SystemAug 31, 2022
76 days to decisionK221745 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k221745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 16, 2022
Decision date	Aug 31, 2022
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Reach Medical Instrument Co, Ltd.
Location	Shanghai, CN
Contact	Mingsha Ye
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Sinow Medical AS
Contact	Huifang Zhao

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/k221745/> 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