FDA 510(k) Premarket Notification

K221745 Sterile Posterior Spinal Fixation System

CLEARED

Aug 31, 2022
76 days to decision

K221745 · 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