FDA 510(k) Premarket Notification

K222031 Spinal Inner Fixation System

CLEARED

Oct 28, 2022
109 days to decision

K222031 · 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