FDA 510(k) Premarket Notification

K230961 Zeus Spinal System

CLEARED

Oct 10, 2023
188 days to decision

K230961 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k230961/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 5, 2023
Decision date	Oct 10, 2023
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Sanyou Medical Co, Ltd.**
Location	Bartlett, TN, US
Contact	David Fan
510(k) history	9 submissions · 9 cleared · 2013-2023

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Christine Scifert

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov