FDA 510(k) Premarket Notification

K240180 Orthopeasia Spinal Fixation System

CLEARED

Aug 30, 2024
220 days to decision

K240180 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k240180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 23, 2024
Decision date	Aug 30, 2024
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthopeasia Co., Ltd.**
Location	Bangpla, Bangplee, Samutprakarn, TH
Contact	Phunyawee Ritshima
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Aztech Regulatory & Quality, LLC**
Contact	Joseph Azary

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