FDA 510(k) Premarket Notification

K190408 Spinal Fixation System

CLEARED

Jun 16, 2020
481 days to decision

K190408 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k190408/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 21, 2019
Decision date	Jun 16, 2020
Days to decision	481 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shangdong Kangsheng Medical Devices Co., Ltd.**
Location	Tai'An City, CN
Contact	Wenxing Dong
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Medwheat (Shanghai) Medical Technology Co. , Ltd.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov