FDA 510(k) Premarket Notification

K200981 Mega Plus MIS Spine System

CLEARED

Aug 11, 2020
119 days to decision

K200981 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k200981/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 14, 2020
Decision date	Aug 11, 2020
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bk Meditech, Co., Ltd.**
Location	Hwasung-Si, Kyunggi-Do, KR
Contact	Byoungjun Park
510(k) history	11 submissions · 11 cleared · 2006-2020

REGULATORY CONSULTANT

Consulting firm	**Emprical Testing Corp.**
Contact	Nathan Wright

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