FDA 510(k) Premarket Notification

K191655 MEGAFIX® Pedicle Screw Spinal System

CLEARED

Mar 6, 2020
259 days to decision

K191655 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k191655/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 21, 2019
Decision date	Mar 6, 2020
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Seohancare Co., Ltd.**
Location	Gimpo-Si, KR
Contact	Chae Lynn Song
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Meredith May

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