

K191655 MEGAFIX® Pedicle Screw Spinal SystemMar 6, 2020
259 days to decisionK191655 · 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](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191655/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 21, 2026