

**K173180 Mega Plus Spine System**Mar 15, 2018  
167 days to decisionK173180 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k173180/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 29, 2017
Decision date	Mar 15, 2018
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Testing Corp</b>
Contact	Meredith L. May

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

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