

K183080 Mega Plus Spine SystemDec 10, 2018
35 days to decisionK183080 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k183080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 5, 2018
Decision date	Dec 10, 2018
Days to decision	35 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	Meredith Lee May
510(k) history	11 submissions · 11 cleared · 2006-2020

REGULATORY CONSULTANT

Consulting firm	Empirical Testing Corp
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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