

K201788 EDEN Spinal Fixation SystemJun 23, 2022
723 days to decisionK201788 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k201788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 30, 2020
Decision date	Jun 23, 2022
Days to decision	723 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jmt Co., Ltd.
Location	Yangju-Si, KR
Contact	Sang-Ok Nam
510(k) history	4 submissions · 4 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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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