FDA 510(k) Premarket Notification

K201793 EDEN Peek Cage

CLEARED

Sep 13, 2021
440 days to decision

K201793 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k201793/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jun 30, 2020
Decision date	Sep 13, 2021
Days to decision	440 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