FDA 510(k) Premarket Notification

K221844 TDM Lumbar Interbody Fusion Cage System

CLEARED

Aug 17, 2022
54 days to decision

K221844 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k221844/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 24, 2022
Decision date	Aug 17, 2022
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tdm Co., Ltd.**
Location	Gwangju, KR
Contact	Jung Wook Choi
510(k) history	11 submissions · 11 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	**Eerkie Corporation**
Contact	Jeena Mathai

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