FDA 510(k) Premarket Notification

CLEARED

K212070 KMTI S141 Lumbar Interbody Fusion System

Aug 30, 2021
59 days to decision

K212070 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k212070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 2, 2021
Decision date	Aug 30, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kyocera Medical Technologies, Inc.**
Location	Redlands, CA, US
Contact	Anthony DeBenedictis
510(k) history	15 submissions · 15 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Nathan Wright

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