FDA 510(k) Premarket Notification

K211689 KEYSTONE PEEK Cage System

CLEARED

Sep 21, 2021
111 days to decision

K211689 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k211689/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 2, 2021
Decision date	Sep 21, 2021
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Sanyou Medical Co, Ltd.**
Location	Bartlett, TN, US
Contact	David Fan
510(k) history	9 submissions · 9 cleared · 2013-2023

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Christine Scifert

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