

K211689 KEYSTONE PEEK Cage SystemSep 21, 2021
111 days to decisionK211689 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211689/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026