FDA 510(k) Premarket Notification

CLEARED

K232069 Expandable Lumbar Fusion Cage (Type I,Type II)

Nov 29, 2023
140 days to decision

K232069 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k232069/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 12, 2023
Decision date	Nov 29, 2023
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Reach Medical Instrument Co, Ltd.**
Location	Shanghai, CN
Contact	Jian Shen
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Shanghai SUNGO Management Consulting Co., Ltd.**
Contact	Eva Li

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