FDA 510(k) Premarket Notification

K234077 SPIRA® Anterior Lumbar Spacers

CLEARED

Jul 12, 2024
203 days to decision

K234077 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k234077/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 22, 2023
Decision date	Jul 12, 2024
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Camber Spine Technologies**
Location	Newtown Square, PA, US
Contact	Brooks McAdam
510(k) history	17 submissions · 17 cleared · 2013-2024

REGULATORY CONSULTANT

Consulting firm	**MRC Global**
Contact	Christine Scifert

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