FDA 510(k) Premarket Notification

K233972 Camber Sacroiliac (SI) Fixation System

CLEARED

Feb 27, 2024
74 days to decision

K233972 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k233972/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 15, 2023
Decision date	Feb 27, 2024
Days to decision	74 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	**Mcra, LLC**
Contact	Justin Eggleton

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