FDA 510(k) Premarket Notification

K203503 Camber Sacroiliac (SI) Fixation System

CLEARED

Sep 2, 2022
641 days to decision

K203503 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k203503/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Nov 30, 2020
Decision date	Sep 2, 2022
Days to decision	641 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Camber Spine Technologies, LLC**
Location	Wayne, PA, US
Contact	Daniel A. Pontecorvo
510(k) history	6 submissions · 6 cleared · 2018-2024

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