FDA 510(k) Premarket Notification

K232256 Alcantara Thoracolumbar Plate System

CLEARED

Apr 16, 2024
263 days to decision

K232256 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k232256/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jul 28, 2023
Decision date	Apr 16, 2024
Days to decision	263 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	Brooks McAdam
510(k) history	6 submissions · 6 cleared · 2018-2024

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