FDA 510(k) Premarket Notification

CLEARED

K231715 MONDRIAN™ Anterior Lumbar Plate System

Jan 26, 2024
227 days to decision

K231715 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k231715/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jun 13, 2023
Decision date	Jan 26, 2024
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ctl Medical Corporation**
Location	Addison, TX, US
Contact	Sean Suh
510(k) history	14 submissions · 14 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	**Omnee Strategic Solutions, Inc.**
Contact	Dhaval Saraiya

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