FDA 510(k) Premarket Notification

K213491 Universal Pilot Guidance Instrument System

CLEARED

May 12, 2022
192 days to decision

K213491 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k213491/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 1, 2021
Decision date	May 12, 2022
Days to decision	192 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	**Omni Strategic Solutions, LLC**
Contact	Dhaval Saraiya

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