FDA 510(k) Premarket Notification

K232572 Kalitec Navigated Instrument System

CLEARED

Dec 13, 2023
111 days to decision

K232572 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k232572/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 24, 2023
Decision date	Dec 13, 2023
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kalitec Direct, LLC Doing Business AS Kalitec Medical**
Location	Orlando, FL, US
Contact	Winn Scott
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**The OrthoMedix Group, Inc.**
Contact	J.D. Webb

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