

K232572 Kalitec Navigated Instrument SystemDec 13, 2023
111 days to decisionK232572 · 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](https://accessdata.fda.gov)

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