

K233299 ExactechGPS® SystemJan 26, 2024
119 days to decisionK233299 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k233299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 29, 2023
Decision date	Jan 26, 2024
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Blue Ortho
Location	La Tronche, FR
Contact	Matthieu Coic
510(k) history	9 submissions · 9 cleared · 2010-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233299/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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