

K232521 ExactechGPS® Total Ankle ApplicationNov 16, 2023
90 days to decisionK232521 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k232521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 18, 2023
Decision date	Nov 16, 2023
Days to decision	90 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/k232521/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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