

**K213546 ExactechGPS Total Shoulder Application, Equinoxe Planning Software**

Jan 6, 2022  
59 days to decision

K213546 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k213546/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 8, 2021
Decision date	Jan 6, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k213546/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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