

K230700 RIWOtrack Navigation SystemNov 20, 2023
252 days to decisionK230700 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k230700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Mar 13, 2023
Decision date	Nov 20, 2023
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fiagon GmbH
Location	Hennigsdorf, DE
Contact	Dirk Mucha
510(k) history	15 submissions · 15 cleared · 2014-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230700/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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