

K223070 Remi Robotic Navigation SystemOct 28, 2022
28 days to decisionK223070 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k223070/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 30, 2022
Decision date	Oct 28, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fusion Robotics, LLC
Location	Louisville, CO, US
Contact	Sarah Braun
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Integrity Implants Inc. Db a Accelus
Contact	Sarah Braun

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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