FDA 510(k) Premarket Notification

K223350 Remi Robotic Navigation System

CLEARED

Mar 13, 2023
131 days to decision

K223350 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k223350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 2, 2022
Decision date	Mar 13, 2023
Days to decision	131 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. Dba Accelus**
Contact	Sarah Braun

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