FDA 510(k) Premarket Notification

K230700 RIWOtrack Navigation System

CLEARED

Nov 20, 2023
252 days to decision

K230700 · 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