FDA 510(k) Premarket Notification

K231494 CoreLink Robotic Navigation Instruments

CLEARED

Oct 27, 2023
157 days to decision

K231494 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k231494/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 23, 2023
Decision date	Oct 27, 2023
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corelink, LLC**
Location	Round Rock, TX, US
Contact	Steven Mounts
510(k) history	35 submissions · 35 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Nathan Wright

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