FDA 510(k) Premarket Notification

K230880 CoreLink Navigation Instruments

CLEARED

May 2, 2023
33 days to decision

K230880 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k230880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Mar 30, 2023
Decision date	May 2, 2023
Days to decision	33 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