FDA 510(k) Premarket Notification

K214059 CoreLink Navigation Instruments

CLEARED

Jan 19, 2022
23 days to decision

K214059 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k214059/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 27, 2021
Decision date	Jan 19, 2022
Days to decision	23 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 Testing Corp**
Contact	Nathan Wright

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