FDA 510(k) Premarket Notification

K182731 Corelink Navigation Instruments

CLEARED

Dec 13, 2019
441 days to decision

K182731 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k182731/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 28, 2018
Decision date	Dec 13, 2019
Days to decision	441 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 D. Mounts
510(k) history	35 submissions · 35 cleared · 2008-2023