FDA 510(k) Premarket Notification

K210472 SPINEART Navigation Instrument System

CLEARED

Mar 19, 2021
30 days to decision

K210472 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k210472/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 17, 2021
Decision date	Mar 19, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spineart**
Location	Geneva, CH
Contact	Franck Pennesi
510(k) history	44 submissions · 44 cleared · 2008-2023