FDA 510(k) Premarket Notification

CLEARED

K212088 Integrity Implants Navigated Instruments

Dec 23, 2021
170 days to decision

K212088 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k212088/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 6, 2021
Decision date	Dec 23, 2021
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Integrity Implants, Inc.**
Location	Jupiter, FL, US
Contact	Lauren Kamer
510(k) history	11 submissions · 11 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	**Telos Partners, LLC**
Contact	Roshana Ahmed

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