FDA 510(k) Premarket Notification

K213876 Spineology Navigation Instruments

CLEARED

Aug 5, 2022
235 days to decision

K213876 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k213876/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 13, 2021
Decision date	Aug 5, 2022
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spineology, Inc.**
Location	Stillwater, MN, US
Contact	Andrew Adams
510(k) history	54 submissions · 51 cleared · 1999-2025