FDA 510(k) Premarket Notification

K233725 Spine Navigation System

CLEARED

Jul 26, 2024
248 days to decision

K233725 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k233725/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 21, 2023
Decision date	Jul 26, 2024
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medivis, Inc.**
Location	Brooklyn, NY, US
Contact	Amy Lynn
510(k) history	3 submissions · 3 cleared · 2019-2025