FDA 510(k) Premarket Notification

K223200 Curiteva Navigation System

CLEARED

Jan 6, 2023
85 days to decision

K223200 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k223200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Oct 13, 2022
Decision date	Jan 6, 2023
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Curiteva, Inc.**
Location	Tanner, AL, US
Contact	Eric Linder
510(k) history	11 submissions · 11 cleared · 2019-2026