FDA 510(k) Premarket Notification

K222510 Blueprint Mixed Reality system

CLEARED

Jan 20, 2023
154 days to decision

K222510 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k222510/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 19, 2022
Decision date	Jan 20, 2023
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tornier S.A.S.**
Location	Bloomington, MN, US
Contact	Moyees Kamara
510(k) history	20 submissions · 19 cleared · 2013-2024