FDA 510(k) Premarket Notification

K212023 Virage Navigation System

CLEARED

Aug 27, 2021
59 days to decision

K212023 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k212023/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 29, 2021
Decision date	Aug 27, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Biomet Spine, Inc.**
Location	Broomfield, CO, US
Contact	David Pollard
510(k) history	15 submissions · 15 cleared · 2017-2021