FDA 510(k) Premarket Notification

K203751 OMNIVision system

CLEARED

Apr 12, 2021
110 days to decision

K203751 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k203751/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 23, 2020
Decision date	Apr 12, 2021
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corin USA**
Location	Tampa, FL, US
Contact	Lucinda Gerber
510(k) history	57 submissions · 57 cleared · 1996-2021

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert A Poggie

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov