FDA 510(k) Premarket Notification

K231611 HOLO Portal™ Surgical Guidance System

CLEARED

Aug 31, 2023
90 days to decision

K231611 · Product code: **SBF** · Orthopedic
Source: https://www.510kdatabase.net/k231611/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Jun 2, 2023
Decision date	Aug 31, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Surgalign Spine Technologies**
Location	Deerfield, IL, US
Contact	Jeremy Markovich
510(k) history	3 submissions · 3 cleared · 2022-2023