FDA 510(k) Premarket Notification

K230567 OptiVu™ ROSA® MxR

CLEARED

Jun 13, 2023
104 days to decision

K230567 · Product code: **SBF** · Orthopedic
Source: https://www.510kdatabase.net/k230567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Mar 1, 2023
Decision date	Jun 13, 2023
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthosoft Inc. (d/b/a) Zimmer CAS**
Location	Montreal, CA
Contact	Mona Mansouri
Website	https://www.zimmerbiomet.com
510(k) history	18 submissions · 18 cleared · 2017-2026