

K230567 OptiVu™ ROSA® MxRJun 13, 2023
104 days to decisionK230567 · 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

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