

K250108 OptiVu™ ShoulderJul 9, 2025
174 days to decisionK250108 · Product code: **SBF** · Orthopedic
Source: <https://www.510kdatabase.net/k250108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Jan 16, 2025
Decision date	Jul 9, 2025
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mr Surgical Solutions, LLC
Location	Conshohocken, PA, US
Contact	Brian Karpinski
510(k) history	3 submissions · 3 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Jalex Medical
Contact	Kyle Kovach

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250108/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026