

K252170 OptiVu™ ShoulderAug 8, 2025
29 days to decisionK252170 · Product code: **SBF** · Orthopedic
Source: <https://www.510kdatabase.net/k252170/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Jul 10, 2025
Decision date	Aug 8, 2025
Days to decision	29 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

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