August 8, 2025

MR Surgical Solutions, LLC
% Kyle Kovach
Quality and Regulatory Manager
JALEX Medical
27865 Clemens Road
Suite #3
Westlake, Ohio 44145

Re: K252170
Trade/Device Name: OptiVu™ Shoulder
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: July 10, 2025
Received: July 10, 2025

Dear Kyle Kovach:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252170

Please provide the device trade name(s).

OptiVu™ Shoulder

Please provide your Indications for Use below.

OptiVu™ Shoulder is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection, and aligning the endoprosthesis with the anatomical structures, provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

OptiVu™ Shoulder utilizes pre-operative planning files provided by the Zimmer CAS Signature ONE™ System. OptiVu™Shoulder is compatible with any humeral implants that are supported by the Signature ONE™ System.

OptiVu™ Shoulder is specifically indicated for total shoulder arthroplasty using the Zimmer Biomet Alliance® Glenoid system or reverse shoulder arthroplasty using the Comprehensive® Reverse Shoulder system, to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection, and aligning the glenoid component with the anatomical structures.

OptiVu Shoulder includes an augmented reality (AR) head-mounted display (HMD) (OptiVu Tilt with HoloLens 2) and trackers to register and optically track anatomical landmarks and surgical instruments in real-time during the procedure. The HMD should not be relied upon solely and should always be used in conjunction with traditional methods.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Special 510(k) Summary

Submitted By:	MR Surgical Solutions, LLC 425 Fayette Street, #617 Conshohocken, PA 19428
Date:	07/10/2025
Contact Person:	Kyle Kovach, Quality and Regulatory Manager
Contact Telephone:	(440) 787-5832
Contact Fax:	(440) 933-7839

Device Trade Name:	OptiVu™ Shoulder
Device Classification Name:	Stereotaxic instrument (21 CFR 882.4560)
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Codes:	SBF
Primary Predicate Device:	OptiVu™ Shoulder (K250108)

Device Description:

OptiVu Shoulder is a stereotaxic surgical navigation system designed to aid surgeons in locating anatomical structures and aligning the endoprosthesis in total or reverse shoulder arthroplasty procedures. The system includes an augmented reality (AR) head-mounted display (HMD) (OptiVu Tilt with HoloLens 2) and mixed reality trackers to register and optically track anatomical landmarks and surgical instruments in real-time during the procedure.

The OptiVu Shoulder system is intended to be used specifically with the Zimmer Biomet Alliance® Glenoid or Comprehensive® Reverse Shoulder system for total or reverse shoulder arthroplasty, respectively.

The OptiVu Shoulder system also utilizes pre-operative planning files provided by the Zimmer CAS Signature ONE™ System.

The intended users of the system are surgeons who are trained in performing shoulder arthroplasty procedures.

Indications for Use:

OptiVu™ Shoulder is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection, and aligning the endoprosthesis with the anatomical structures, provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

OptiVu™ Shoulder utilizes pre-operative planning files provided by the Zimmer CAS Signature ONE™ System. OptiVu™ Shoulder is compatible with any humeral implants that are supported by the Signature ONETM System.

OptiVu™ Shoulder is specifically indicated for total shoulder arthroplasty using the Zimmer Biomet Alliance® Glenoid system or reverse shoulder arthroplasty using the Comprehensive® Reverse Shoulder system, to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection, and aligning the glenoid component with the anatomical structures.

OptiVu Shoulder includes an augmented reality (AR) head-mounted display (HMD) (OptiVu Tilt with HoloLens 2) and trackers to register and optically track anatomical landmarks and surgical instruments in real-time during the procedure. The HMD should not be relied upon solely and should always be used in conjunction with traditional methods.

Summary of Technological Characteristics:

The OptiVu Shoulder subject instruments and the predicate device instruments both have the same indications for use and fundamental scientific technology. The purpose of this Special 510(k) submission is to update both the packaging parameters for the instruments and the site for contract sterilization. A condensed comparison table of the subject and predicate device technological characteristics is presented below. There are no differences in technological characteristics that raise questions of safety and efficacy.

Table 1: Indications for Use and Technological Characteristics Comparison

	Subject Device: OptiVu™ Shoulder	**Predicate Device: OptiVu™ Shoulder (K250108)**	**Comparison**
Classification Name	Stereotaxic Instrument	Stereotaxic Instrument	Equivalent
Regulation Number	§882.4560	§882.4560	Equivalent
Product Code	SBF	SBF	Equivalent
Regulation Medical Specialty	Orthopedic	Orthopedic	Equivalent
Materials	Stainless steel, Makrolon	Stainless steel, Makrolon	Equivalent
Indications for Use	OptiVu™ Shoulder is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection,	OptiVu™ Shoulder is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection,	Equivalent

	and aligning the endoprosthesis with the anatomical structures, provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan. OptiVu™ Shoulder utilizes pre-operative planning files provided by the Zimmer CAS Signature ONE™ System. OptiVu™ Shoulder is compatible with any humeral implants that are supported by the Signature ONETM System. OptiVu™ Shoulder is specifically indicated for total shoulder arthroplasty using the Zimmer Biomet Alliance® Glenoid system or reverse shoulder arthroplasty using the Comprehensive® Reverse Shoulder system, to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection, and aligning the glenoid component with the anatomical structures. OptiVu Shoulder includes an augmented reality (AR) head-mounted display (HMD) (OptiVu Tilt with HoloLens 2) and trackers to register and optically track anatomical landmarks and surgical instruments in real-time during the procedure. The HMD should not be relied upon solely and should always be used in conjunction with traditional methods.	and aligning the endoprosthesis with the anatomical structures, provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan. OptiVu™ Shoulder utilizes pre-operative planning files provided by the Zimmer CAS Signature ONE™ System. OptiVu™ Shoulder is compatible with any humeral implants that are supported by the Signature ONETM System. OptiVu™ Shoulder is specifically indicated for total shoulder arthroplasty using the Zimmer Biomet Alliance® Glenoid system or reverse shoulder arthroplasty using the Comprehensive® Reverse Shoulder system, to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection, and aligning the glenoid component with the anatomical structures. OptiVu Shoulder includes an augmented reality (AR) head-mounted display (HMD) (OptiVu Tilt with HoloLens 2) and trackers to register and optically track anatomical landmarks and surgical instruments in real-time during the procedure. The HMD should not be relied upon solely and should always be used in conjunction with traditional methods.	

Device Description	OptiVu Shoulder is a stereotaxic surgical navigation system designed to aid surgeons in locating anatomical structures and aligning the endoprosthesis in total or reverse shoulder arthroplasty procedures. The system includes an augmented reality (AR) head-mounted display (HMD) (OptiVu Tilt with HoloLens 2) and mixed reality trackers to register and optically track anatomical landmarks and surgical instruments in real-time during the procedure. The OptiVu Shoulder system is intended to be used specifically with the Zimmer Biomet Alliance® Glenoid or Comprehensive® Reverse Shoulder system, for total or reverse shoulder arthroplasty, respectively. The OptiVu Shoulder system also utilizes pre-operative planning files provided by the Zimmer CAS Signature ONE™ System. The intended users of the system are surgeons who are trained in performing shoulder arthroplasty procedures.	OptiVu Shoulder is a stereotaxic surgical navigation system designed to aid surgeons in locating anatomical structures and aligning the endoprosthesis in total or reverse shoulder arthroplasty procedures. The system includes an augmented reality (AR) head-mounted display (HMD) (OptiVu Tilt with HoloLens 2) and mixed reality trackers to register and optically track anatomical landmarks and surgical instruments in real-time during the procedure. The OptiVu Shoulder system is intended to be used specifically with the Zimmer Biomet Alliance® Glenoid or Comprehensive® Reverse Shoulder system, for total or reverse shoulder arthroplasty, respectively. The OptiVu Shoulder system also utilizes pre-operative planning files provided by the Zimmer CAS Signature ONE™ System. The intended users of the system are surgeons who are trained in performing shoulder arthroplasty procedures.	Equivalent
Packaging	Double sterile barrier	Single sterile barrier	Substantially Equivalent
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Equivalent

These aspects of the subject device were determined to be equivalent to the previous generation of the device as the two systems compare similarly in:

- Regulatory Characteristics and Intended Use/Indications for Use
- Device Function/Performance
- Materials and Manufacturing Processes
- Design Features/Dimensions
- Post-Processing Procedures, including Sterility and Shelf-Life Characteristics

Validation Testing:

With the updated packaging and sterilization parameters presented in this submission, there are no technological or design changes in the subcomponents of the OptiVu Shoulder system instruments themselves. In an effort to demonstrate that there is no impact on risk or safety of the devices due to the updated packaging and sterilization, validation testing was conducted according to written protocols with acceptance criteria that were based on established standards. This submission includes or references the following tests in support of a substantial equivalence determination:

- Sterilization validation testing to confirm that there is no impact to the sterilization efficacy of the system
- Packaging validation to confirm that the packaging of OptiVu Shoulder system is safe and effective

Conclusion:

Based on the indications for use, intended use, principle of operation, technological characteristics of software for navigation and surgical instruments, and performance evaluation, the subject OptiVu Shoulder system has demonstrated substantial equivalence to the predicate OptiVu Shoulder system. Any differences between the subject device and cited predicate system do not raise new questions of safety or effectiveness and validation activities demonstrate that the OptiVu Shoulder system is at least as safe and effective as the legally marketed predicate device.