July 9, 2025

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

Re: K250108
Trade/Device Name: OptiVu™ Shoulder
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: July 8, 2025
Received: July 8, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250108

Device Name

OptiVu™ Shoulder

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitted By:	MR Surgical Solutions, LLC 425 Fayette Street, #617 Conshohocken, PA 19428
Date:	07/08/2025
Contact Person:	Kyle Kovach, Senior Quality and Regulatory Engineer
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:	Pixee Medical Knee+ (K243975)
Additional Predicate Devices:	Medacta International SA NextAR RSA Platform (K210153) Orthosoft Inc (d/b/a Zimmer CAS) ROSA® Shoulder System (K233199)

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 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.

Summary of Technological Characteristics:

OptiVu Shoulder and the predicate devices both have the same indications for use and fundamental scientific technology. A comparison table of the subject device and predicate device technological characteristics is provided in this submission in Section 004 Substantial Equivalence Discussion. A condensed comparison table is also 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	**Primary Predicate: Pixee Medical Knee+ (K243975)**	**Additional Predicate: NextAR™ RSA Platform (K210153)**	**Additional Predicate: Orthosoft Inc (d/b/a Zimmer CAS) ROSA® Shoulder System (K233199)**	**Comparison**
Classification Name	Stereotaxic Instrument	Stereotaxic Instrument	Stereotaxic Instrument	Stereotaxic Instrument	Equivalent
Regulation Number	§882.4560	§882.4560	§882.4560 §888.3030 §892.2050 §888.3660	§882.4560	Equivalent
Product Code	SBF	SBF	OLO, PBF, LLZ, PHX	OLO, LLZ	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, 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	Knee+ is a stereotaxic system including an intraoperative software as a medical device and surgical instruments. Knee+ is intended for primary Total Knee Replacement, to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position the cutting guide regarding computed mechanical axis. The Knee+ includes smart glasses as a	The Shoulder NextAR™ RSA Platform supports the surgeon during glenoid implantation in reverse shoulder replacement procedures providing information on bone preparation, instrument guidance, and implant positioning. The Shoulder NextAR™ RSA Platform works in conjunction with NextAR™ stereotaxic	The ROSA® Shoulder System, for use with the ROSA® RECON platform, is indicated as a stereotaxic instrumentation system for Total Shoulder Arthroplasty (TSA) surgery. It is used to assist the surgeon in providing software-defined spatial boundaries for orientation and reference to identifiable anatomical structures for the accurate placement of the	Substantially Equivalent

	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.	Head Mounted Device (HMD) for displaying information to the user intraoperatively. The smart glasses should not be relied upon solely and should always be used in conjunction with traditional methods.	instruments and general surgical instruments to implant the Medacta Shoulder System Reverse (RSA – Reverse Shoulder Arthroplasty). As an optional display, the smart glasses can be used auxiliary to the Shoulder NextAR™ Platform to view the same 2D stereotaxic information as presented by the Shoulder NextAR™ Platform. The Shoulder NextAR™ stereotaxic instruments are to support the surgeon during specific orthopedic surgical steps by providing information on bone preparation, instrument guidance, and Implant positioning. Once registered, the NextAR™ stereotaxic instruments provide reference to a patient's rigid anatomical structures on the surface of the glenoid that are identified relative to preoperative C.T. based planning. The smart glasses should not be relied upon solely and should always be used in conjunction with the primary computer display.	shoulder implant components. The robotic arm placement is performed relative to anatomical landmarks and bony anatomy as recorded using the system intraoperatively, and based on a three-dimensional representation of the bone structures determined pre-operatively using compatible CT based imaging technology. It includes a robotic arm, an optical sensor navigation system and accessories, software system, surgical instruments and accessories. The ROSA® Shoulder System is designed for use on a skeletally mature patient population. The target population has the same characteristics as the population targeted by the implants compatible with the ROSA® Shoulder System. The ROSA® Shoulder System is to be used with the following shoulder replacement systems in accordance with their indications and contraindication:	

				• Humerus implants: Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, Identity® Shoulder System and Identity® Reverse Shoulder System. • Glenoid implants: Alliance™ Glenoid and Comprehensive® Reverse Shoulder System.	
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.	Knee+ is a navigation system dedicated to orthopaedic knee surgery. It includes KneePlus software and KneeTools reusable surgical instruments. The main purpose of Knee+ is to assist the surgeon during primary Total Knee Arthroplasty (TKA) interventions. Knee+ provides information to help locate and orientate the main femoral and tibial cutting planes as required during TKA. Knee+ allows the surgeon to adjust the orientation of the cutting plane orientation and the level of resection by collecting anatomical references during the TKA procedure using surgical instruments. The software locates in a 3D reference frame the instruments which include markers. All	The Shoulder NextAR™ RSA Platform is a CT based computer-assisted surgical navigation platform used to perform a reverse shoulder arthroplasty on the glenoid and includes the following components: -PC based hardware platform; (K193559 and K202152) -optical tracking system; (K193559 and K202152) -Augmented Reality glasses; (K193559 and K202152) -Platform (K193559 and K202152) -navigation software which displays information to the surgeon in real-time; -Reusable surgical instruments to perform the surgical steps of a shoulder reverse arthroplasty on the glenoid.	The ROSA® Shoulder system (RSS) for use with ROSA® RECON Platform (cleared via K230243) is used to assist surgeons in performing Total Shoulder Arthroplasty (TSA) for both anatomic and reverse techniques. It features humeral resection and glenoid reaming capabilities to reproduce the preoperative plan intraoperatively with use of intra-operative anatomical registration. The RSS uses a Non-Device Medical Device Data System (MDDS) called the Zimmer Biomet Portal, which manages the creation and tracking of surgical cases. The cases with the pre-operative planning based on surgeon preferences reside on the portal until they are uploaded to the ROSA	Substantially Equivalent

	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.	collected coordinates are treated by software algorithms to provide the surgeon with relevant orientation and location of the tracked cutting guide. Knee+ software is installed on a wearable Head Mounted Device (HMD) which includes a camera, a computer and displays intraoperative information to the user. A near-eye display allows the surgeon to look at the HMD screen when needed.	The system operates on the common principle of stereotaxic technology in which markers are mounted on the bones and an infrared camera is used to monitor the spatial location of the markers. Tracking sensors attached to the scapula and surgical instruments enable the surgeon to view the position and orientation of scapula and instrumentation relative to preoperative data in real-time while performing the surgical procedure. The tracking sensors are provided sterile. Shoulder NextAR™ RSA Platform aids the surgeon in executing the surgical plan by visualizing all the information in real time on a screen monitor. The NextAR™ RSA system is intended to assist the surgeon in executing a preoperative surgical planning. The navigation platform tracks the surgical instruments in real-time and displays intraoperative and planned surgical parameters on a screen, thus allowing the surgeon to match the intraoperative parameters with the planned ones.	RECON Platform before surgeries. The intra-operative workflow and surgical concepts implemented in the system remain close to the conventional TSA workflow. As such, at the time of the surgery, the system mainly assists the surgeon in (1) determining reference alignment axes in relation to anatomical landmarks, (2) planning the orthopedic implants location intraoperatively based on these reference alignment axes and orthopedic implant geometry, and (3) precisely position the humeral cut guide and glenoid reamer relative to the planned orthopedic implant location by using a robotic arm.	

			Specifically, the navigation system utilizes established technologies of navigation and via an active infrared camera rigidly coupled with the scapula and an active infrared tracker that can be rigidly coupled to the surgical instruments. The registration of the patient's scapula on the preoperative scapula model is performed through the use of dedicated surgical instruments (pointers) and a dedicated registration algorithm.		

Non-Clinical Testing:

In an effort to demonstrate safety and effectiveness of the OptiVu Shoulder System, non-clinical 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:

- Performance tests to ensure the performance of the implemented features and verify related design inputs
- Engineering analysis to ensure the performance of the implemented features and verify related design inputs
- Usability engineering to address user interactions with the OptiVu Shoulder system
- Validation lab to validate that the OptiVu Shoulder system is safe and effective and performance of the system is acceptable under full simulated use on cadaveric specimens
- Software verification to ensure all design outputs meet all specified requirements
- Software validation to ensure software specifications conform to user needs and intended uses

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 device systems. Any differences between the subject device and cited predicate systems do not raise new questions of safety or effectiveness and verification and validation activities demonstrate that the OptiVu Shoulder system is at least as safe and effective as the legally marketed predicate devices.