February 6, 2026

Balmoral Medical LLC
% Lorry Weaver
Principal Consultant
Qserve Group US, Inc.
350 S. Main Street
Suite 309
Doylestown, Pennsylvania 18901

Re: K252058
Trade/Device Name: ROSA Knee System with UltraSound Imaging Platform (USIP)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 30, 2025
Received: January 8, 2026

Dear Lorry Weaver:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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
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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.

510(k) Number *(if known)*
K252058

Device Name
ROSA Knee System with UltraSound Imaging Platform (USIP)

Indications for Use *(Describe)*
ROSA Knee System with USIP for use with ROSA RECON platform, is indicated as a stereotaxic instrumentation system for total knee replacement (TKA) surgery. It is to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of knee implant components. The robotic arm placement is performed relative to the position and orientation of the femur and tibia as tracked by the ultrasound and optical systems. It is also based on the surgical plan specified by the surgeon intra-operatively on the robot user interface. To be able to perform this tracking, a virtual 3D bone model of the patient's femur and tibia are generated pre-operatively from a CT-scan of their leg.
The ROSA Knee System with USIP is designed for use on skeletally mature patient population. It includes an ultrasound imaging system, a robotic arm, an optical sensor navigation system and accessories, surgical instruments, and a software system. It does not include a pre-operative planning feature.
The ROSA Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: Persona® CR, Persona PS, Persona Ti-Nidium® CR, Persona Ti-Nidium PS and Persona IQ® The Smart Knee™.

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.

510(k) Summary – [21 CFR 807.92]

807.92(a)(1), (2), (3)

Date Prepared: February 4, 2026

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Device Trade Name: ROSA® Knee System with Ultrasound Imaging Platform

Common Name: Orthopedic Stereotaxic Instrument

Review Panel: Office of Orthopedic Devices (OHT6C)

Classification Name: Orthopedic Stereotaxic Instrument

Regulation No.: 882.4560

Classification Code: OLO

Predicate Device: **ROSA® Knee System**: 510(k) K182964
Classification Code: OLO
Regulation: 882.4560

Reference Device: **SonoVision Ultrasound Imaging System**: 510(k) K192388
Classification Code: IYO, ITX
Regulation: 892.1550

Reference Device: **JointVue 3D Echo**: 510(k) K211656
Classification Code: IYO, LLZ
Regulation: 892.2050

Device Description *807.92(a)(4)***:**

The ROSA® Knee System with USIP (Ultrasound Imaging Platform) is used to assist surgeons in performing Total Knee Arthroplasty (TKA) with features to assist with the bone resections. The USIP device is to be used with the Zimmer Biomet ROSA Knee System to perform TKA. The USIP device provides an ultrasound-based location solution for tibia and femur replacing the use of fluted pins placed in the femur and tibia. The USIP is composed of the ultrasound acquisition box, which connects to the ROSA Knee System and two belts; femur and tibia, which contain the ultrasound transducers. NavitrackERs are mounted on the femur and tibia belts and calibrated to locate the bone relative to the robot. The belts wrap or partially wrap the thigh

(femur belt) and the calf (tibia belt) of the patient. The belts image the patient's bone via the ultrasound transducers contained in the belts.

Indications for Use *[Intended Use 807.92(a)(5)]***:**

ROSA Knee System with USIP for use with ROSA RECON platform, is indicated as a stereotaxic instrumentation system for total knee replacement (TKA) surgery. It is to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of knee implant components. The robotic arm placement is performed relative to the position and orientation of the femur and tibia as detected by the ultrasound and tracked by the optical systems. It is also based on the surgical plan specified by the surgeon intra-operatively on the robot user interface. To be able to perform this real-time bone detection, a virtual 3D bone model of the patient's femur and tibia are generated pre-operatively from a CT-scan of their leg.

The ROSA Knee System with USIP is designed for use on skeletally mature patient population. It includes an ultrasound imaging system, a robotic arm, an optical sensor navigation system and accessories, surgical instruments, and a software system. It does not include a pre-operative planning feature.

The ROSA Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: Persona® CR, Persona PS, Persona Ti-Nidium® CR, Persona Ti-Nidium PS and Persona IQ® The Smart Knee™.

Technological Characteristics *807.92(a)(6)***:**

ROSA Knee System with USIP and the primary predicate, ROSA Knee System cleared under K182964, have the same intended use. Functionally, both devices are orthopedic stereotaxic instruments used to assist surgeons in performing Total Knee Arthroplasty (TKA). Stereotaxic tracking is performed using the same components as the predicate with a rigid frame using the optical tracking camera, tracking arrays (NavitrackERs), and computer. Features include assistance with the planning and executing of bone resections. The intraoperative workflow and surgical concepts implemented with the USIP remain close to the conventional (non-robotically assisted) TKA workflow. At the time of the surgery and based on the surgical plan, both the predicate and subject device assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in planning the orthopedic implant's location based on the reference alignment axes and orthopedic implant geometry, and in precisely positioning the Cut Guide relative to the planned orthopedic implant location by using a Robotic Arm.

The primary difference between the predicate device (ROSA Knee System) and the subject device (ROSA Knee with USIP) is how the relative position between the optical guide and the patient's bony anatomy is determined and tracked. Specifically,

the USIP device accomplishes both tasks with the same method, continuous, non-invasive, ultrasonic bone detection wherein ultrasonic waves are transmitted through the soft tissue to continuously track the location of the patient's bone. This not only allows registration between the patient's bony anatomy and the optical guide, but it also additionally provides real time tracking of the bony anatomy. The USIP device provides a non-invasive tracking solution for the tibia and femur that replaces the use of fluted bicortical pins screwed into the femur and tibia. ROSA with USIP uses B-mode ultrasound to identify the location of the bones (femur and tibia) from ultrasound technology that detects stationary body tissue characteristics, such as depth and location of tissue interfaces.

To address this difference, reference device SonoVision (K192388) provides comparison of the similar technological characteristics that the ultrasound technology in ROSA with USIP employs for the bone detection aspect of the tracking system. SonoVision is similar to the USIP real-time 2D bone scanning feature. SonoVision employs real-time 2D bone scanning with the ability to highlight and enhance bone anatomy, as well similar acoustic output following Track 1 ultrasound standards. JointVue 3D Echo (K211656) shares the equivalent feature of 3D surface contouring visualization of ultrasound volume data derived from the ultrasound system. The transducers associated with JointVue 3D use similar frequency as USIP.

Similarities between reference devices and the subject device include shared elements of the intended use as a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging in musculoskeletal applications. B-mode imaging with linear array ultrasound transducers, and generation of ultrasound images of stationary body tissue location and characteristics. The reference devices and subject device all meet the acoustic output requirements according to FDA guidance *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* for the applications used.

Differences between the ROSA Knee with USIP and the reference devices include:

- USIP has a lower acoustic intensity than SonoVision.
- The frequency ranges are different however, similar in range (12-3 MHz vs 10-5 MHz) as needed for musculoskeletal applications.
- USIP ultrasound transducers (femur and tibia belts) are affixed to the patient and intended to be immovable during use, whereas SonoVision transducers are handheld and typically moved by the healthcare professional while generating an image.

Summary of Non-Clinical Test - Performance and Safety Testing *807.92(b)(1)***:**

FDA guidance, *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, February 21, 2023,* applicable to ultrasound component reference product codes IYO and ITX has been followed. ROSA Knee with USIP was evaluated and found to meet performance standards and requirements for

performance, biocompatibility, electrical, electromagnetic, acoustic, and stereotaxic features.

Validation

An evaluation of performance between cadaveric and predicate data in the clinical environment and workflow was performed. Quantitative analysis demonstrated that tissue-related imaging was substantially equivalent to the predicate device.

Verification

Accuracy was established as part of design verification to confirm system performance verifying design inputs were met under fully simulated benchtop use conditions.

Software Verification and Validation

Software tests were conducted to satisfy requirements of the FDA Guidance *Content Premarket Submissions for Device Software Functions* and IEC 62304 (*Medical Device Software - Life Cycle Processes)*. ROSA® Knee System with USIP Software could lead to serious injury to the patient prior to the implementation of risk control measure in the event of a software failure. Therefore, it is concluded that the documentation level of the ROSA Knee System with USIP Software is Enhanced. The software testing demonstrates that the ROSA Knee System with USIP does not raise any new issues of safety and effectiveness as compared to the predicate device.

Biocompatibility

The body contacting materials of the device meet biocompatibility requirements according to ISO 10993-1 5th edition 2018-08 for transient exposure (< 24 hours per the ISO guideline and typically ≤ 2 hours in the actual clinical application), external communicating device.

Cleaning, Reprocessing, Disinfection

Reprocessing of ROSA Knee with USIP tibia and femur belts comply with *FDA Guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling; March 17, 2015*.

Electrical Safety and EMC

ROSA Knee with USIP meets the requirements of the applicable elements of the following safety and EMC standards.

- AAMI ES60601-1:2005 + A1:2012 + A2:2010 + C1:2009 + A2:2021 *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + A1:2012 + A2:2020 + US differences)*

- IEC 62359: edition 2.1 2019-09 consolidated - *Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*
- IEC 60601-2-37: edition 2.1 2015 - *Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*
- IEC 60601-1-2: edition 4.1 2020-09 consolidated – *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

Summary of Clinical Tests *807.92(b)(2)***:**
Clinical performance testing was not conducted.

Conclusion *807.92(b)(3)***:**

ROSA® Knee System with USIP (Ultrasound Imaging Platform) and the predicate, ROSA® Knee System (K182964) are orthopedic stereotaxic instruments under regulation 882.4560, product code OLO. The intended use and key technological characteristics of the entire ROSA Knee System with USIP is substantially equivalent; they share the surgical robot with optical tracking system and the NavitrackER. Functionally, both devices assist surgeons in performing Total Knee Arthroplasty (TKA) with features to assist with the planning and execution of bone resections by tracking bones real-time.

The differences between the devices do not raise new and/or different questions of safety and effectiveness. Both devices share the same instrument tracking and optical array tracking. While there are technological differences in regard to the patient connection method, this difference does not raise different questions, and the company has provided data to demonstrate equivalent performance.

Unlike the predicate, the ROSA Knee System with USIP incorporates ultrasound imaging whose technological characteristics are comparable to reference devices SonoVision (K192388) and JointVue 3D Echo (K211656). The ultrasound 2D B-mode real-time imaging and linear array transducers used to generate ultrasound images of stationary body tissue location and characteristics are similar to SonoVision. The USIP also similarly uses point cloud matched to the CT-based 3D model of the patient’s bone, similar to the 3D images that are generated with JointVue 3D. The emitted ultrasonic energy conforms to applicable safety standards and performance data in a simulated clinical workflow validates the intended use

ROSA Knee System with USIP was evaluated for electrical, thermal, mechanical, and EMC safety. Cleaning/disinfection, biocompatibility, and acoustic output have

been evaluated, and the device has been found to conform to applicable mandatory medical device safety standards.

In conclusion, the ROSA® Knee System with USIP can be found equivalent to its predicate device.