November 13, 2025

Kruti Gosalia
Regulatory Affairs Specialist
75 Queen Street Suite 3300
Montreal, QC H3C 2N6
Canada

Re: K251314
Trade/Device Name: Rosa® Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 28, 2025
Received: October 14, 2025

Dear Kruti Gosalia:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251314

Device Name
Rosa® Knee System

Indications for Use *(Describe)*
The ROSA Knee System, for use with the ROSA® RECON platform, is indicated as a stereotaxic instrumentation system for total knee replacement 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 anatomical landmarks as recorded using the system intraoperatively, and based on a surgical plan optionally determined pre-operatively using compatible X-ray based surgical planning tools.

It includes a robotic arm, an optical tracking system and accessories, software system, surgical instruments and accessories.

The ROSA Knee System is designed for use on skeletally mature patient population. The targeted population has the same characteristics as the population that is suitable for the implants compatible with the ROSA Knee System.

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the ROSA® Knee System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance documents, 'Format for Traditional and Abbreviated 510(k)s', issued on September 13, 2019.

Sponsor:

Orthosoft, Inc (d/b/a. Zimmer CAS)
75 Queen St., Suite 3300
Montreal, QC, CANADA H3C 2N6
Establishment Registration Number: 9617840

Contact Person:

Kruti Gosalia
Regulatory Affairs Specialist
Telephone: +1 (617) 309 0575

Date:

November 12, 2025

Subject Device:

Trade Name: ROSA® Knee System
Common Name: ROSA® Knee System

Classification Name:

- OLO – Orthopedic Stereotaxic Instrument (21 CFR 882.4560)

Predicate Device(s):

Manufacturer	Device Name	510(k) Number
Zimmer CAS	ROSA® Knee System	K242864

Purpose and Device Description:

The ROSA® Knee System for use with the ROSA® RECON platform is used to assist surgeons in performing Total Knee Arthroplasty (TKA) with features to assist with the bone resections as well as assessing the state of the soft tissues to facilitate implant positioning intra-operatively.

The ROSA® Knee System 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 reside on the portal until they are uploaded to the ROSA® RECON Platform before surgeries.

If the case is image-based, a 3D virtual bone model is generated pre-operatively by the PSI system (X-PSI Knee System-K171269) to create a 3D model of the patient's femur/tibia and allows the preparation of a pre-operative surgical plan as well as visualization of planned cuts. The pre-operative plan is then

matched to the landmarks taken intra-operatively on the patient's bony anatomy. An imageless option is also available where landmarks taken intra-operatively on the patient's bony anatomy are used to create the surgical plan. Accuracy of resections, knee state evaluation, and soft tissue assessment are the same between image-based and imageless options as they are always based on intra-operative landmarks.

The intraoperative workflow and surgical concepts implemented in the ROSA Knee System remain close to the conventional TKA 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 based on these reference alignment axes and orthopedic implant geometry (planning optionally based on a pre-operative plan using pre-operative imaging), and (3) precisely positioning the cut guide relative to the planned orthopedic implant location by using a robotic arm.

The purpose of this submission is to (1) add additional compatible FDA-cleared knee implant systems, Persona® PPS® CR, Persona® PPS® PS, Persona® SoluTion PPS. As a result of this change, the labeling and Indications for Use has been updated to include this compatibility with these implant systems. (2) New instrumentation is being added to the subject device. (3) Improvements have been made to the Software Development Kit (SDK) (4) Improvement of existing features and addition of new features within the ROSA Knee Software Application.

Indications for Use:

The ROSA Knee System, for use with the ROSA® RECON platform, is indicated as a stereotaxic instrumentation system for total knee replacement 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 anatomical landmarks as recorded using the system intraoperatively and based on a surgical plan optionally determined pre-operatively using compatible X-ray based surgical planning tools. It includes a robotic arm, an optical tracking system and accessories, software system, surgical instruments and accessories. The ROSA Knee System is designed for use on skeletally mature patient population. The targeted population has the same characteristics as the population that is suitable for the implants compatible with the ROSA Knee System. The ROSA Knee System is to be used with the following fixed bearing knee replacement in accordance with their indications and contraindications: NexGen® CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona® CR, Persona® PS, Persona Ti-Nidium® CR, Persona Ti-Nidium PS,

Persona® PPS® CR, Persona® PPS® PS, Persona® SoluTion PPS, Persona IQ®, Vanguard® CR, and Vanguard PS.

Contraindications:

The ROSA® Knee System may not be suitable for use in case of:

- hip pathology with significant bone loss (e.g. avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum);
- hip pathology severely limiting range of motion (e.g. arthrodesis, severe contractures, chronic severe dislocation);
- active infections of the knee joint area;
- knee replacement revision surgery;
- presence of strong infrared sources or infrared reflectors in the vicinity of the trackers;
- contraindications for the implant as given by the implant manufacturer;
- implants that are not compatible with the system

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on the consideration of the following characteristics:

- The proposed and predicate device are intended to assist the surgeon in providing software-defined spatial boundaries for orientation.
- The proposed and predicate device assist in the intraoperative navigation of the patient's anatomy and are utilized to facilitate implant positioning.
- The proposed and predicate device assists in joint balancing techniques.
- The proposed and predicate device utilize image data that has been segmented to create a 3D model of the patient's bony anatomy.
- The proposed and predicate device share the same previously cleared ROSA RECON Platform, and the proposed and predicate device consists of major components including a software system, navigation system, various instrumentation including reusable and disposable.

Summary of Performance Data (Nonclinical and/or Clinical)

The following performance date was provided in support of the substantial equivalence determination:

Biocompatibility Testing:

The biocompatibility evaluation for ROSA Knee was conducted in accordance with ISO 10993. The evaluation reveals that the ROSA Knee device meets biocompatibility requirements.

Electrical Safety and Electromagnetic Compatibility (EMC):

No new testing was deemed necessary on the ROSA RECON Platform.

Device Performance Testing

- **Physical/Performance Test(s):** These tests were documented through Design Verification Reports to ensure the performance of the implemented features and verify related design inputs.
- **Verification Analysis:** These tests were documented through Verification Analysis Reports to ensure the performance of the implemented features and verify related design inputs.
- **Engineering Analysis:** These tests were documented through Engineering Rationales to ensure the performance of the implemented features and verify related design inputs.
- **Integration test at system level:** integration test at the system level such as integrating the robot and instruments in the software
- **Validation Lab:** Performed to validate that using the ROSA Knee System is safe and effective and that the performances of the ROSA Knee System are acceptable under full simulated use on cadaveric specimens.
- **Usability Engineering:** addressed user interactions with the Rosa Knee System

Software Verification and Validation Testing

Software tests were conducted to satisfy requirements of the FDA Guidance for the Content Premarket Submissions for Device Software Functions and IEC 62304 (Medical Device Software - Life Cycle Processes). ROSA® Knee System 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 Software is Enhanced. The software testing demonstrates that the ROSA Knee System does not raise any new issues of safety and effectiveness as compared to the predicate device.

Substantial Equivalence Conclusion:

Both the proposed device and predicate device have the same intended use and similar indications for use. The proposed device and predicate utilize the same platform components. The technological characteristics between the proposed device and predicate are similar with differences in the software application features, software development kit (SDK) and the addition of new instrumentation with the proposed device. In summary, any differences between the devices do not raise new questions of safety and effectiveness and the proposed device is at least as safe and effective as the legally marketed predicate device.