



October 18, 2024

Orthosoft Inc. (d/b/a) Zimmer CAS
Nilam Dave
Regulatory Affairs Specialist
75 Queen Street Suite 3300
Montreal, QC H3C 2N6
Canada

Re: K242864
Trade/Device Name: ROSA® Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 20, 2024
Received: September 20, 2024

Dear Nilam Dave:

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

Submission Number (if known)

K242864

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 (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 anatomical landmarks as recorded using the system intraoperatively, and based on a surgical plan optionally determined pre-operatively using compatible X-ray or MRI 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 IQ®, 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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, ‘The Special 510k Program Guidance for Industry and Food and Drug Administration Staff’, issued on September 13, 2019, ‘Deciding When to Submit a 510(k) for a Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff’, issued on October 25, 2017, and ‘Deciding When to Submit a 510(k) for a Software Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff’, issued on October 25, 2017.

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

Contact Person: Nilam Dave
Regulatory Affairs Specialist
Telephone: +1 (206) 638-8947

Date: September 20, 2024

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	K230243

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 systems (X-PSI Knee System-K171269 or CAS PSI Knee System-K131409) 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 the submission is additional compatibility (Persona IQ 30 mm) with the FDA cleared tibial extension implant (stem), Canturio Smart Extension with Canary Health Implanted Reporting Processor (CHIRP) System, FDA 510(k) number K234056 to the subject device: ROSA Knee System.

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 (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 anatomical landmarks as recorded using the system intraoperatively, and based on a surgical plan optionally determined pre-operatively using compatible X-ray or MRI 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 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 consideration of the following characteristics:

- **Intended Use:** Same as predicate device
- **Indications for Use:** Same as predicate device
- **Technological Characteristics:** Same as predicate device. The subject device adds the additional compatibility of the Persona IQ 30 mm stem to the system.
- **Principle of Operation:** Same as predicate device

Summary of Performance Data (Nonclinical and/or Clinical)

The existing performance data that was performed for the predicate device remains unchanged and is still applicable for the proposed device.

Substantial Equivalence Conclusion:

The subject device, ROSA Knee System, has the same Intended Use, Indications for Use, technological characteristics, and performance data as its predicate device, ROSA Knee System (K230243) and the information provided demonstrates: In sum, 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.