April 22, 2022

Orthosoft, Inc (d/b/a Zimmer CAS)
Paul Hardy
Associate Director
75 Queen St, Suite 3300
Montreal, QC H3C 2N6
Canada

Re: K213708
Trade/Device Name: ROSA® Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 21, 2022
Received: January 24, 2022

Dear Paul Hardy:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213708

Device Name
ROSA® Knee System

Indications for Use *(Describe)*
The ROSA® Knee System 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 sensor navigation system and accessories, software system, surgical instruments and accessories.

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 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.

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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, *The Special 510k Program, Guidance for Industry and Food and Drug Administration Staff*, 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:

Paul Hardy
Regulatory Affairs Associate Director
Telephone: (574) 453-6739

Date:

November 23, 2021

Subject Device:

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

Classification Name:

- OLO – Orthopedic Stereotaxic Instrument (21 CFR 882.4560)

Predicate Device:

Manufacturer	Device Name	510(k) Number
Zimmer CAS	ROSA Knee	K182964

Purpose and Device Description:

The ROSA® Knee System 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 (Non-Device-MDDS) called the

Zimmer Biomet Drive Portal which manages the creation and tracking of surgical cases. The cases reside on the portal until they are uploaded to the ROSA® Knee System 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 or CAS PSI Knee System) to create a model of the patient's femur/tibia and allows for the preparation of a pre-operative surgical plan. An image-free 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 image-free options as they are always based on intra-operative landmarks.

The intraoperative workflow and surgical concepts implemented in the system remain close to the conventional TKA workflow. As such, at the time of the surgery and based on the surgical plan, the system mainly assists the surgeon for 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, assisting in joint balancing, and precisely positioning the cut guide relative to the planned orthopedic implant location by using a robotic arm.

The purpose of this submission is to add an additional compatible FDA cleared knee implant system, the Canary Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP) System, also known as Persona IQ. As a result of this change, the labeling and Indications for Use has been updated to include this compatibility with this additional knee implant system.

Indications for Use:

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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.

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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 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; and
- 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:** The Indications for Use of the proposed device and predicate are identical except for

the addition of a new implant to the list of compatible implant systems
- **Technological Characteristics:** Same as predicate device
- **Principle of Operation:** Same as predicate device

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - An analysis of the performance testing was conducted which followed similar test methods and acceptance criteria to those used for the predicate device. The analysis demonstrated that the subject device did not impact the existing design inputs, user needs, or intended use.

Substantial Equivalence Conclusion

The proposed and predicate device have the same intended use, technological characteristics and the same principles of operation. The Indications for Use of the proposed device and predicate are identical except for the addition of a new implant to the list of compatible implant systems. 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.