November 16, 2023

Orthosoft d/b/a Zimmer CAS
Rakhi Toravane
Regulatory Affairs Specialist
75 Queen Street, Suite 3300
Montreal, QC H3C 2N6
Canada

Re: K232533
Trade/Device Name: ROSA Partial Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 18, 2023
Received: August 21, 2023

Dear Rakhi Toravane:

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.

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)*
K232533

Device Name
ROSA Partial Knee System

Indications for Use *(Describe)*
The ROSA® Partial Knee System, for use with the ROSA® RECON platform, is indicated as a stereotaxic instrumentation system for Partial Knee replacement (PKA) 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 the knee implant components.

The robotic arm placement is performed relative to anatomical landmarks as recorded using the system intraoperatively, and based on a three-dimensional representation of the bone structures determined preoperatively using compatible X-ray or MRI based imaging technologies.

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

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

The ROSA® Partial Knee System is to be used with Persona Partial Knee (PPK) fixed bearing knee replacement system in accordance with its indications and contraindications.

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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K232533

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® Partial Knee (PKA) System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, '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, H3C 2N6, CANADA
Establishment Registration Number: 9617840

Contact Person:

Rakhi Toravane
Regulatory Affairs Specialist
Telephone: 647-407-9164

Date:

18th August 2023

Subject Device:

Trade Name: ROSA® Partial Knee System
Common Name: ROSA® Partial Knee System, ROSA® PKA System

Classification Name:

- OLO-Stereotaxic Instrument (21 CFR 882.4560)

Predicate Device:

510(k) Number	Device Name	Manufacturer
K210121	ROSA® Partial Knee System	Zimmer CAS

Purpose and Device Description:

The ROSA® Partial Knee System for use with the ROSA® RECON Platform is used to assist surgeons in performing Partial Knee Arthroplasty (PKA) with features to assist with the bone resections as well as assessing the state of the soft tissues to facilitate implant positions intraoperatively.

The system uses a Non-Device Medical Device Data System (MDDS) called the Zimmer Biomet Drive Portal which manages the creation and tracking of the surgical cases. The cases resides on the portal until it is 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 or CAS PSI Knee System) to create a 3D model of the patient's femur/tibia and allows the preparation of a pre-operative ROSA® Total Knee System (TKA) surgical plan. However, the pre-operative surgical plan is not provided in the ROSA® Partial Knee System and is only made available if a switch is performed intra-operatively from ROSA® Partial Knee System to the ROSA® Knee System. Landmarks taken intra-operatively on the patient's bony anatomy are used to create the intra-operative surgical plan.

An image-less 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 intra-operative workflow and surgical concepts implemented in the system remain close to the conventional PKA 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 using pre-operative imaging), and (3) precisely positioning the cut guide relative to the planned orthopedic implant location by using a robotic arm and (4) using the Zimmer Biomet Persona Partial Knee (PPK) spacer block to perform the femoral distal cut

Indications for Use:

The ROSA® Partial Knee System, for use with the ROSA®RECON platform, is indicated as a stereotaxic instrumentation system for Partial Knee replacement (PKA) 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 the knee implant components.

The robotic arm placement is performed relative to anatomical landmarks as recorded using the system intraoperatively, and based on a three-dimensional representation of the bone structures determined preoperatively using compatible X-ray or MRI based imaging technologies.

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

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

The ROSA® Partial Knee System is to be used with Persona Partial Knee (PPK) fixed bearing knee replacement system in accordance with its indications and contraindications.

Contraindications:

The ROSA® Partial 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 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:

- The proposed and predicate device are intended to assist the surgeon in providing software defined spatial boundaries for orientation
- The proposed and predicate device assists in 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 utilizes image data that has been segmented to create a 3D model of the patient's bony anatomy
- The proposed and predicate device utilize the 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 data was provided in support of the substantial equivalence determination:

Biocompatibility Testing

No additional testing was deemed necessary. The existing biocompatibility testing is still applicable for the proposed device. The biocompatibility assessment specific to the existing standard Persona Partial Knee instrumentation as well as for the existing ROSA® Partial Knee instruments remain valid as per their original clearance and are not altered through their use in conjunction with the ROSA® Partial Knee System workflow application.

Electrical Safety and Electromagnetic Compatibility (EMC)

No additional testing was deemed necessary on the ROSA® RECON Platform. The existing EMC testing is still applicable to the subject device.

Device Performance Testing

Verification and Validation Testing for ROSA® Partial was conducted with the following aspects:

- Physical/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
- Validation Lab- performed to validate that using ROSA® Partial Knee System is equivalently safe and effective and that the performances of the system are acceptable under full simulated use on cadaveric specimens.

Software Verification and Validation Testing

Software tests were conducted to satisfy requirements of the FDA Guidance for the Content Premarket Submissions for Software Contained in Medical Devices and IEC 62304 (Medical Device Software- Life Cycle Process). The software was considered a "major" level of concern, since a failure of the software could result in serious injury or death to the patient. The documentation that was provided is enhanced as a failure or flaw of any device software

function(s) could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use The testing demonstrates that the ROSA® Partial 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 identical Indications for use/intended use and principle of operation. The technological characteristics between the proposed device and the predicate are similar, with differences in the addition of Persona Partial Knee standard instrumentation in the cutting system and software workflow.

However, the information provided herein demonstrates that:

- Any differences do not raise new questions of safety and effectiveness;
- Verification and Validation activities demonstrate that the proposed device is at least as safe and effective as the legally marketed predicate device.