April 19, 2021

Orthosoft d/b/a Zimmer CAS
Kavina Veeren
Regulatory Affairs Manager
75 Queen Street, Suite 3300
Montreal, Quebec H3C 2N6
Canada

Re: K210121
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: January 15, 2021
Received: January 19, 2021

Dear Kavina Veeren:

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,

For: 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)*
K210121

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 optionally 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.

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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® 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 August 12, 2005.

Sponsor:

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

Contact Person:

Kavina Veeren
Manager, Regulatory Affairs
Telephone: (514-245-8906)

Date:

15th January 2021

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(s):

510(k) Number	Device Name	Manufacturer
K182964	ROSA® Knee System	Zimmer CAS *Primary
K170584	MAKO Partial Knee Application	MAKO Surgical Corp.

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) on the medial compartment with features to assist with the bone

resections as well as assessing the state of the soft tissues to facilitate implant positioning intraoperatively.

The ROSA® Partial Knee 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 reside 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-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 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.

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 optionally 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;

o presence of strong infrared sources or infrared reflectors in the vicinity of the trackers;

o contraindications for the implant as given by the implant manufacturer; and

o 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(s) are intended to assist the surgeon in providing software defined spatial boundaries for orientation
- The proposed and predicate device(s) assists in intraoperative navigation of the patient's anatomy and are utilized to facilitate implant positioning
- The proposed and predicate device(s) assists in joint balancing techniques
- The proposed and predicate device(s) utilizes image data that has been segmented to create a 3D model of the patient's bony anatomy
- The proposed and primary predicate device utilize the ROSA® RECON Platform, and the proposed and predicate device(s) 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

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

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety and EMC testing was conducted on the ROSA® RECON Platform. The device complies with recognized electrical safety standards: IEC 60601-1 standard for electrical safety and IEC 60601-1-2 standard for electromagnetic compatibility.

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
- Usability Engineering- addressed user interactions with ROSA® Partial Knee System
- Validation Lab- performed to validate that using ROSA® Partial Knee System is 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 testing demonstrates that the ROSA® Partial Knee System does not raise any new issues of safety and effectiveness as compared to the predicate device(s).

Substantial Equivalence Conclusion

The proposed and predicate device(s) have the same intended use and similar technological characteristics including that the proposed device utilizes Magnetic Resonance (MR) and X-ray image data, which is the same as the primary predicate device. The MAKO predicate device uses Computed Tomography (CT).

In addition, the proposed device uses cutting blocks to assist with bone preparation similar to traditional manual partial knee arthroplasty which is similar to the primary predicate device. The MAKO predicate device is equipped with an automated cutting system that does not require cutting blocks.

The proposed device does not perform any pre-operative surgical planning as compared to the predicate devices. The primary predicate and proposed device share the same previously cleared ROSA® RECON platform hardware and software core components and some of the same instrumentation between the two systems.

In summary, 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(s).