August 17, 2021

Orthosoft d/b/a Zimmer CAS
Paul Hardy
Regulatory Affairs Associates Director
75 Queen Street, Suite 3300
Montreal, Quebec H3C 2N6
Canada

Re: K210998
Trade/Device Name: ROSA Hip System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, OLO
Dated: July 12, 2021
Received: July 13, 2021

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of in vitro Diagnostics
and Radiological Health
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)*
K210998

Device Name
ROSA® Hip System

Indications for Use *(Describe)*
The ROSA® Hip System for use with the ROSA® RECON platform, is indicated as a fluoroscopic-guided system for total hip arthroplasty (THA). It is used to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of hip implant components provided that the points of interest can be identified from radiology images.

The intraoperative cup placement is performed relative to anatomical landmarks as recorded using the system intraoperatively, and based on preoperative planning values optionally determined using compatible X-Ray based surgical planning tools.

The ROSA® Hip 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® Hip System. The ROSA® Hip System is not for primary image interpretation and is applicable for the direct anterior approach.

The ROSA® Hip System is to be used with the following hip replacement systems in accordance with their indications and contraindications: G7® Acetabular System, Avenir® Hip System, Avenir Complete™ Hip System, Taperloc® Complete Hip System, Echo® Hip System.

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.

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® Hip 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:

Paul Hardy
Regulatory Affairs Associate Director
Telephone: 574-453-6739
Paul.Hardy@zimmerbiomet.com

Date:

August 17, 2021

Subject Device:

Trade Name: ROSA® Hip System
Common Name: ROSA® Hip System, ROSA Hip, ROSA® THA System

Classification Name:

- LLZ - Medical Image Management And Processing System (21 CFR 892.2050)
- OLO - Stereotaxic Instrument (21 CFR 882.4560)

Predicate Devices:

Manufacturer	Device Name	510(k) Number
JointPoint, Inc.	JointPoint *primary	K160284
Zimmer CAS	ROSA® Knee System	K182964

Purpose and Device Description:

The ROSA® Hip System (RHS) for use with the ROSA® RECON platform is used to assist surgeons in performing Total Hip Arthroplasty (THA) with features to assist in acetabular shell impaction for the direct anterior approach, as well as assessing the leg length discrepancy and the femoral offset.

The ROSA® Hip System uses a Non-Device Medical Device Data System (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® RECON Platform before surgeries. The ROSA® Hip System utilizes the robotic arm of the ROSA® RECON platform cleared in K182964, but does not add new stereotaxic or robotic components

The system uses fluoroscopic images to determine the instruments' orientation in relation to the patient anatomy and as a guide for acetabular component orientation. The system allows the surgeon to input the case's surgical pre-operative planning values and preview the acetabular component orientation intra-operatively. Throughout the surgical workflow, fluoroscopic images are acquired with a C-arm. Fluoroscopic images are then captured with the ROSA® Tablet and transferred onto ROSA®. The current instruments' orientation is computed from the image capture and is adjusted to match the surgeon's planning values using the ROSA® RECON robotic arm. The system provides pre, intra and post-operative measurements relative to patient anatomy and does not provide infrared-based stereotaxic navigation for implant placement. The robotic arm is maintained stationary to keep the instruments in a fixed orientation during acetabular component impaction. The system also provides component selection options based on leg length and offset discrepancies measurements.

The intra-operative workflow and surgical concepts implemented in the system remain close to the conventional THA direct anterior approach workflow. As such, at the time of the surgery, the system mainly assists the surgeon in (1) determining reference alignment axes and cup orientation using image-to-image and robotic

registration, (2) precisely orienting the cup inserter relative to the desired orthopedic implant angle by using a robotic arm, and (3) providing leg length and offset discrepancies measurements based on fluoroscopic image references.

Indications for Use:

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Contraindications:

The ROSA® Hip 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)
- active infections of the hip joint area
- hip replacement revision surgery
- presence of undesirable radio-opaque element during intra-operative image acquisition

- 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 devices have the same intended uses and similar indications for use. The devices are intended to assist surgeons in the accurate positioning & placement of hip or knee components.
- The proposed and JointPoint predicate device utilize a C-arm and digital tablet to acquire intraoperative fluoroscopic images for patient registration and positioning of hip implant components.
- The proposed and ROSA predicate device share the same previously cleared ROSA® RECON Platform, and the proposed and ROSA predicate device consists of major components including a software system, various instrumentation including reusable and disposable. The proposed and ROSA predicate use the robotic arm on the ROSA® RECON Platform to assist the guidance of instruments.
- The proposed and primary predicate allow users to mark and adjust landmarks within the software for assessment of leg length and offset for the hip implant components

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 Hip was conducted in accordance with ISO 10993. The evaluation reveals that the ROSA Hip 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 Hip 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 Hip System
- Validation Lab- performed to validate that using ROSA Hip 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 Hip System does not raise any new issues of safety and effectiveness as compared to the predicate and reference device(s).

Substantial Equivalence Conclusion

The proposed and predicate devices have the same intended use and similar indications for use as the systems are used to assist surgeons in the accurate positioning & placement of hip or knee components. The proposed and primary predicate device utilize fluoroscopic images acquired from a C-arm for patient registration and

intraoperative hip positioning. The proposed and primary predicate also obtain similar landmarks, allows a user to perform overlays, and provides assessment of leg length and offset.

The proposed device does not perform any pre-operative surgical planning and does not assist with any cutting as compared to the ROSA predicate device. The ROSA predicate and proposed device share the same previously cleared ROSA RECON platform hardware and software core components. In addition, the proposed device and ROSA predicate use the robotic arm to assist the guidance of instruments.

In summary, any differences between the devices does not raise new questions of safety and effectiveness and verification and validation activities demonstrate that the proposed device is at least as safe and effective as the legally marketed predicate devices.