Orthosoft, Inc (d/b/a Zimmer CAS)
℅ Victorien Thiaux
Regulatory Affairs Sr. Analyst
75 Queen St., Suite 3300
Montreal, Quebec H3C 2N6
CANADA

May 23, 2023

Re: K231162
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: April 21, 2023
Received: April 24, 2023

Dear Victorien Thiaux:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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)*

K231162

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.

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® 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:

Victorien Thiaux
Regulatory Affairs Sr. Analyst
Telephone: +1 (819) 580-0189
Victorien.Thiaux@zimmerbiomet.com

Date:

April 21, 2023

Subject Device:

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

Classification Name:

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

Predicate Device(s):

Manufacturer	Device Name	510(k) Number	Predicate or Reference
Zimmer CAS	ROSA® Hip System	K210998	Predicate

Purpose and Device Description:

The ROSA® Hip System (RHS) (cleared via K210998) 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 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 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 device. Fluoroscopic images are then captured with the ROSA® Tablet digital camera and transferred onto the ROSA® RECON platform via a wireless connection. 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 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 changes measurements.

The proposed device provides additional compatibility that allows the ROSA® Hip System Software to display images from flat panel C-arm devices onto the Optical Unit monitor throughout the surgical workflow. Images are captured with the ROSA® Tablet digital camera and landmarks are selected to display the outline of either the Lesser or Greater Trochanter.

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 changes measurements based on fluoroscopic image references.

Indications for Use:

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.

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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:

- **Intended Use:** Same as predicate device
- **Indications for Use:** The Indications for Use of the proposed device and predicate are identical
- **Technological Characteristics:** The technological characteristics between the proposed device and predicate device are similar with differences in the modifying features within the ROSA Hip System Software workflow and additional C-arm compatibility.
- **Principle of Operation:** Same as predicate device

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  The performance testing conducted on the predicate is still applicable to the proposed device and remains unchanged. Verification and validation activities including integration testing for the newly compatible Flat Panel C-arm, were performed using the same methods as the predicate device.

Substantial Equivalence Conclusion

Both the proposed and predicate device have identical intended use, indications for use and utilize the same platform components. The technological characteristics between the proposed device and predicate device are similar with differences in the modifying features within the ROSA Hip System Software workflow and additional C-arm compatibility.

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