February 21, 2024

Orthosoft Inc (d/b/a Zimmer CAS)
Sankalp Dere
Regulatory Affairs Project Manager
75 Queen Street Suite 3300
Montreal, QC H3C 2N6
Canada

Re: K233199
Trade/Device Name: ROSA® Shoulder System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: January 18, 2024
Received: January 22, 2024

Dear Sankalp Dere:

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,

Tejen D. Soni -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233199

Device Name
ROSA® Shoulder System

Indications for Use *(Describe)*
The ROSA® Shoulder System, for use with the ROSA RECON platform, is indicated as a stereotaxic instrumentation system for Total Shoulder Arthroplasty (TSA) surgery. It is used to assist the surgeon in providing software-defined spatial boundaries for orientation and reference to identifiable anatomical structures for the accurate placement of the shoulder implant components.

The robotic arm placement is performed relative to anatomical landmarks and bony anatomy as recorded using the system intraoperatively, and based on a three-dimensional representation of the bone structures determined pre-operatively using compatible CT based imaging technology.

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

The ROSA Shoulder System is designed for use on a skeletally mature patient population. The target population has the same characteristics as the population targeted by the implants compatible with the ROSA Shoulder System.

The ROSA Shoulder System is to be used with the following shoulder replacement systems in accordance with their indications and contraindications:
• Humerus implants: Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, Identity® Shoulder System and Identity® Reverse Shoulder System.
• Glenoid implants: Alliance™ Glenoid and Comprehensive® Reverse Shoulder 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 Shoulder 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.

<table>
<tr><td>Sponsor:</td><td>Orthosoft Inc (d/b/a. Zimmer CAS)
75 Queen Street, Suite 3300
Montreal, QC, Canada H3C 2N6
Establishment Registration Number: 9617840</td></tr>
<tr><td>Contact Person:</td><td>Sankalp Dere
Regulatory Affairs Project Manager
SankalpSanjay.Dere@zimmerbiomet.com</td></tr>
<tr><td>Date:</td><td>27 SEP 2023</td></tr>
<tr><td>Subject Device:</td><td>Trade Name: ROSA® Shoulder System
Common Name: ROSA Shoulder System, ROSA Shoulder, ROSA TSA System

Classification Name:
• OLO - Orthopedic Stereotaxic Instrument (21 CFR 882.4560)
• LLZ - Medical image management and processing system (21 CFR 892.2050)</td></tr>
<tr><td>Predicate Device:</td><td>
<table>
<tr><th>Device</th><th>Manufacturer</th><th>510(k) Number</th><th>Predicate or Reference</th></tr>
<tr><td>ExactechGPS Total Shoulder Application, Equinoxe Planning Software</td><td>Blue Ortho</td><td>K213546</td><td>Primary Predicate</td></tr>
<tr><td>ROSA Knee System</td><td>Zimmer CAS</td><td>K230243</td><td>Secondary Predicate</td></tr>
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</td></tr>
<tr><td>Purpose and Device Description:</td><td>The ROSA® Shoulder system (RSS) for use with ROSA® RECON Platform (cleared via K230243) is used to assist surgeons in performing Total Shoulder Arthroplasty (TSA) for both anatomic and reverse techniques. It features humeral resection and glenoid reaming capabilities to reproduce the preoperative plan intraoperatively with use of intra-operative anatomical registration.</td></tr>
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	The RSS uses a Non-Device Medical Device Data System (MDDS) called the Zimmer Biomet Portal, which manages the creation and tracking of surgical cases. The cases with the pre-operative planning based on surgeon preferences reside on the portal until they are uploaded to the ROSA RECON Platform before surgeries. The intra-operative workflow and surgical concepts implemented in the system remain close to the conventional TSA 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 intra-operatively based on these reference alignment axes and orthopedic implant geometry, and (3) precisely position the humeral cut guide and glenoid reamer relative to the planned orthopedic implant location by using a robotic arm.
Indications for Use:	The ROSA® Shoulder System, for use with the ROSA® RECON platform, is indicated as a stereotaxic instrumentation system for Total Shoulder Arthroplasty (TSA) surgery. It is used to assist the surgeon in providing software-defined spatial boundaries for orientation and reference to identifiable anatomical structures for the accurate placement of the shoulder implant components. The robotic arm placement is performed relative to anatomical landmarks and bony anatomy as recorded using the system intraoperatively, and based on a three-dimensional representation of the bone structures determined pre-operatively using compatible CT based imaging technology. It includes a robotic arm, an optical sensor navigation system and accessories, software system, surgical instruments and accessories. The ROSA® Shoulder System is designed for use on a skeletally mature patient population. The target population has the same characteristics as the population targeted by the implants compatible with the ROSA® Shoulder System. The ROSA® Shoulder System is to be used with the following shoulder replacement systems in accordance with their indications and contraindications: • Humerus implants: Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, Identity® Shoulder System and Identity® Reverse Shoulder System. • Glenoid implants: Alliance™ Glenoid and Comprehensive® Reverse Shoulder System.

Contraindications:	The ROSA® Shoulder System may not be suitable for use in case of: • Shoulder pathologies with significant bone loss • Shoulder pathology severely limiting range of motion • Active infections of the shoulder joint area • Shoulder replacement revision surgery • Presence of strong infrared sources or infrared reflectors in the vicinity of the trackers • Contraindications for the implants as given by the implant manufacturer • Implants that are not compatible with the system • Presence of pre-existing radio-opaque elements that could interfere with pre-operative image acquisition or intra-operative registration
Summary of Technological Characteristics:	The rationale for substantial equivalence is based on consideration of the following characteristics: • Indications for Use/Intended Use: The proposed device has the same intended use and similar indications for use as the predicates. The devices are intended to assist surgeons by providing software-defined spatial boundaries for orientation, and reference information to relative anatomical structures for accurate implant component placement. • The proposed and the predicates allow users for patient bone registration within the software and use it to guide instruments intra-operatively in real time using similar navigation system. • The proposed and ROSA predicate device share the same previously cleared ROSA RECON Platform with its major core hardware and software components, tracking 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 assist surgeon using similar intra-operative instruments guiding to perform the glenoid reaming based on the surgeon's plan.
Summary of Performance Data (Nonclinical and/or Clinical):	The following performance date was provided in support of the substantial equivalence determination: **Biocompatibility Testing** The biocompatibility evaluation for ROSA Shoulder System was conducted in accordance with ISO 10993. The evaluation shows that the ROSA Shoulder devices meets biocompatibility requirements. **Electromagnetic Compatibility (EMC) and Electrical Safety**

	Electrical Safety and EMC testing was conducted on the ROSA RECON Platform. The device complies with recognized standards: IEC 60601-1, IEC 60601-1-2 & IEC 60601-1-6 standards. **Device Performance Testing** Verification and Validation Testing for ROSA Shoulder System was conducted with the following aspects: • 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 Shoulder System • Validation Lab- performed to validate that using ROSA Shoulder 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 Device Software Functions and IEC 62304 (Medical Device Software - Life Cycle Processes). The software was considered an "Enhanced" Documentation Level, since a failure of the software could result in serious injury or death to the patient. The testing demonstrates that the ROSA Shoulder System does not raise any new issues of safety and effectiveness as compared to the predicate devices.
Substantial Equivalence Conclusion:	Both the proposed device and predicate devices have the same intended use and similar indications for use and are used to guide instrumentation to assist with orthopedic surgery. The technological characteristics between the proposed device and the primary predicate are similar with bone registration and intra-operatively instrument guidance with live tracking. The proposed device does not perform any pre-operative surgical planning as is the case with primary predicate. The proposed ROSA Shoulder System and the secondary ROSA predicate utilize the same ROSA RECON Platform with its core hardware and software 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 do 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.