May 21, 2026

Orthosoft Inc. (d/b/a) Zimmer CAS
Viviana Hernandez
Regulatory Affairs Senior Specialist
75 Queen St. Suite 3300
Montreal, QC H3C 2N6
Canada

Re: K260582
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: February 20, 2026
Received: February 20, 2026

Dear Viviana Hernandez:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260582

Please provide the device trade name(s).

ROSA® Shoulder System

Please provide your Indications for Use below.

The ROSA Shoulder System, for use with the ROSA Recon Platform, is indicated as a stereotaxic instrument 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 intra-operatively, 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 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 per 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

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) #: K260582

510(k) Summary

Prepared on: 2026-05-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Orthosoft Inc. (d/b/a) Zimmer CAS
Applicant Address	75 Queen Street Suite 3300 Montreal QC H3C 2N6 Canada
Applicant Contact Telephone	(57)3203421248
Applicant Contact	Ms. VIVIANA HERNÁNDEZ
Applicant Contact Email	VIVIANA.HERNANDEZ@ZIMMERBIOMET.COM

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ROSA® Shoulder System
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	882.4560
Product Code(s)	OLO, LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233199	ROSA® Shoulder System	OLO

Device Description Summary

21 CFR 807.92(a)(4)

The ROSA® Shoulder system (RSS) for use with ROSA® RECON Platform (cleared via K251314) 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.

The RSS uses a Non-Device Medical Device Data System (MDDS) called the Zimmer Biomet Case Management 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 Shoulder System 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ROSA Shoulder System, for use with the ROSA Recon Platform, is indicated as a stereotaxic instrument 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 intra-operatively, 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 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 per 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

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use / Intended Use remain unchanged since predicate clearance in K233199. The proposed and predicate device are indicated as a stereotaxic instrumentation system for Total Shoulder Arthroplasty (TSA) surgery. They are also 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.

Technological Comparison 21 CFR 807.92(a)(6)

The rationale for substantial equivalence is based on consideration of the following characteristics:

• The proposed device has the same intended use and indications for use as the predicate. The devices are intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during shoulder orthopedic surgery procedures. Both devices are indicated as stereotaxic instrument systems for total shoulder arthroplasty (TSA) surgery.

• The subject device and the predicate allow users for patient bone registration within the software and use it to guide instruments intra-operatively in real time using the same navigation system.

• The proposed and 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 predicate device assist surgeon using similar intra-operative instruments guiding to perform the humeral resection and glenoid reaming based on the surgeon's plan.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance testing and analyses were completed and are submitted in support of the proposed device. Complete test reports have been included and are referenced in each test summary.

The verification of the ROSA® Shoulder System was conducted with the following aspects:
• Physical/Performance Test(s): These tests were documented through Design Verification Protocols and Reports to ensure the performance of the implemented features and verify related design inputs.
• Engineering/Verification Analysis: These tests were documented through Verification Analysis Protocols and Reports or Engineering Rationales to ensure the performance of the implemented features and verify related design inputs.

The validation of the ROSA® Shoulder System was conducted with the following aspects:

• Usability Validation: Performed to confirm the adequacy of the user interface and validate that the full workflow of the ROSA" Shoulder System can be used as safely and effectively by the intended user, in the intended use environment. Fifteen (15) surgeons were able to complete a minimum of two (2) complete simulated Total Shoulder Arthroplasty (TSA) surgical workflows as per the User Manual and complete potential hazard-related tasks. There was no observed use errors associated with critical tasks. All other observations were analyzed and were further mitigated as appropriate within the subject device Control Measures. All test participants deemed the training content adequate. Therefore, all acceptance criteria were met and so the ROSA® Shoulder system is considered validated for usability by the intended user, in the intended environment.
• System Validation: Performed to validate that the full workflow of the ROSA" Shoulder System is as safe and effective and that the performance of the System is acceptable under full simulated use on cadaveric specimens. Fifteen (15) surgeons were able to complete a minimum of two (2) complete simulated Total Shoulder Arthroplasty (TSA) surgical workflows as per the User Manual. A debriefing session was then held with each user, and the ROSA Shoulder System User Needs in scope of the evaluation were validated through a

series of targeted discussions/questions. All evaluated User Needs were successfully validated. Therefore, the acceptance criteria were met and so the ROSA® Shoulder system is considered validated for User Needs by the intended user, in the intended environment.

They are divided into six different groups:
1. System Performance Tests
2. System Engineering and Verification Analyses
3. Hardware Performance Tests
4. Hardware Engineering and Verification Analyses
5. Usability Validation
6. System Validation

No clinical testing was required in support of this premarket notification; therefore, this section is not applicable to this submission.

Verification and Validation testing conducted for the ROSA® Shoulder System confirms that the proposed modifications do not introduce new or different questions of safety or effectiveness. The performance evaluations demonstrate that the subject device meets its predetermined acceptance criteria and performs comparably to the identified predicate device. Therefore, the evidence supports that the proposed device is at least as safe, as effective, and performs as well as the legally marketed predicate.

PREDETERMINED CHANGE CONTROL PLAN (PCCP)

The 510(k) submission includes a Predetermined Change Control Plan (PCCP) to update the ROSA Shoulder System compatibility to include the following additional shoulder implant system components: Comprehensive® Nano Stemless Shoulder (K182516), Identity® Shoulder System (K240876), Identity® Revision Humeral Stems (K251098) and OsseoFit® Stemless Shoulder System (K241873).

Consequently, the labeling and ROSA Shoulder Software (20-8087-700-00) will be modified to incorporate these additional compatibilities. The intended use, patient population, principal of operation, technical characteristics including planning process, software workflow, instrumentation and hardware are unchanged.

Specifically, the new implants for PCCP implant compatibility will be available through the same menus in Planning Panel with the same planning features.

Additionally, after the implementation of this PCCP, the new indications for use will include a list of the new devices: Comprehensive® Nano Stemless Shoulder, Identity® Shoulder System, Identity® Revision Humeral Stems and OsseoFit® Stemless Shoulder System.

The introduction of new implants compatibility to the planning panel of the ROSA Shoulder Software application does not introduce a new worst-case for the ROSA Shoulder System. Given that the proposed change does not introduce new risks or use tasks, the verifications, validation and usability including ROSA Shoulder System performance specifications presented in the subject submission remain applicable with the execution of similar bench testing with same acceptance criteria including:
- Software planning panel verification with the new implant components
- Implant components compatibility verification
- Labeling verification
- Integration test

Overall, the implant compatibility addition PCCP change does not raise new or different questions of safety and effectiveness and that it would be maintained with verification and validation activities described in the PCCP.