February 4, 2026

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

Re: K260104
Trade/Device Name: Signature™ ONE System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: QHE, KWT, KWS, PHX, MBF, HSD
Dated: January 6, 2026
Received: January 13, 2026

Dear Nilam Dave:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Farzana Sharmin -S

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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.	K240106

Please provide the device trade name(s).

Signature™ ONE System

Please provide your Indications for Use below.

The Signature™ ONE System is indicated, based on patient-specific radiological images with identifiable placement anatomical landmarks, to assist in pre-operative planning and/or intra-operative guiding of surgical instruments for shoulder replacement surgical procedures on patients not precluded from being radiologically scanned.

The Signature™ ONE 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 Signature™ ONE System.

The Signature™ ONE System is to be used with the glenoid components of the following shoulder implant systems in accordance with their indications and contraindications: Zimmer® Trabecular Metal Reverse Plus® Shoulder, Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, Comprehensive® Reverse Augmented Baseplates and Alliance® Glenoid System.

The Signature™ ONE System pre-operative planning is also compatible with the humeral components of the following shoulder implant systems in accordance with their indications and contraindications: Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, and Identity™ Shoulder System.

The Signature™ ONE System Guides and bone models are intended for single use only.

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)

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 Signature™ ONE System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance documents, 'The Special 510k Program Guidance for Industry and Food and Drug Administration Staff', issued on September 13, 2019, 'Deciding When to Submit a 510(k) for a Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff', issued on October 25, 2017, and 'Deciding When to Submit a 510(k) for a Software Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff', issued on October 25, 2017.

Sponsor:

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

Contact Person:

Nilam Dave
Regulatory Affairs Specialist
Telephone: +1 (206) 638-8947

Date:

06 Jan 2026

Subject Device:

Trade Name: Signature™ ONE System
Common Name: Signature™ ONE System, ONE Planner Shoulder

Classification Name:

- QHE– Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)

Additional Product Codes:

- KWT- Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650)
- KWS- Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
- PHX- Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
- MBF- Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3670)
- HSD- Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR 888.3690)

Predicate Device:

510(k) Number	Device Name	Manufacturer
K232425	Signature™ ONE System	Zimmer CAS

Purpose and Device Description:

The Signature™ ONE System is developed to assist in pre-operative planning (using the Signature™ ONE Planner) and to accurately transfer a pre-operative plan to orthopedic surgical procedures (using the Signature™ ONE Guides and bone model) if desired in skeletally mature individuals for Total Shoulder Arthroplasty. Both anatomic and reverse (TSA and RSA respectively) approaches are supported.

The Signature ONE Guides and Bone Models are designed and manufactured of polyamide (nylon) using additive manufacturing selective laser sintering (SLS), based on the approved/finalized pre-surgical plan and shipped prior to surgery. The guides and bone models are provided non-sterile and sterilized at the hospital. They are used intra-operatively to assist the surgeon in reproducing the plan on the scapula. The Signature ONE System surgical technique remains close to the conventional shoulder arthroplasty workflow.

The Signature™ ONE System uses a Non-Device Medical Device Data System (MDDS) called the Zimmer Biomet Portal for the interaction with external users (i.e. imaging technician and the surgeon). The internal users (i.e. the Zimmer Biomet operators) use manufacturing software applications to prepare the patient cases for the surgeon.

The purpose of the submission is that the CT Reconstruction internal software application was updated with an improved AI/ML locked model for automatic segmentation and also retraining the model with new production grade scapula and humerus CT segmentations. The AI/ML model is used in the Segmentation step only within the CT Reconstruction internal software application prior to manual segmentation performed by the Zimmer Biomet operator. The use of AI has not changed since predicate K232425. In addition, the Landmarking step within the internal software application was updated with option to select additional configurable landmarks in the Planning application (used to determine the reference coordinate systems to provide native bone information).

The overall Intended Use, Indications for Use, manufacturing process, materials, sterilization methods, principle of operation, and software workflow have not changed from the predicate K232425.

Indications for Use:

The Signature™ ONE System is indicated, based on patient-specific radiological images with identifiable placement anatomical landmarks, to assist in pre-operative planning and/or intra-operative guiding of surgical instruments for shoulder replacement surgical procedures on patients not precluded from being radiologically scanned.

The Signature™ ONE 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 Signature™ ONE System.

The Signature™ ONE System is to be used with the glenoid components of the following shoulder implant systems in accordance with their indications and contraindications: Zimmer® Trabecular Metal Reverse Plus® Shoulder, Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, Comprehensive® Reverse Augmented Baseplates and Alliance® Glenoid System.

The Signature™ ONE System pre-operative planning is also compatible with the humeral components of the following shoulder implant systems in accordance with their indications and contraindications: Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, and Identity™ Shoulder System.

The Signature™ ONE System Guides and bone models are intended for single use only.

Summary of Technological Characteristics:

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

- **Intended Use/ Indications for Use:** Same as predicate device
- **Principle of Operation:** The subject and predicate devices both utilize pre-operative images, and

intraoperative guidance of instruments. The Principle of Operation remains unchanged since device clearance in K232425.

- **Guides/Bone Models:** The subject and predicate device utilize 3D printing (SLS) to manufacture the guides. The guides are non-sterile single use and have a shelf life of 6 months. The existing guides and bone models remain unchanged since predicate clearance K232425.
- **Technological Characteristics:** The subject and predicate device have similar technological characteristics (e.g. image modality, anatomical site, hardware components, and input file type) from the predicate device cleared in K232425.
- **Software Workflow:** The subject and predicate device utilize internal manufacturing software applications and an external software planning application that the surgeon interacts with to review, modify and approve the plan. The overall fundamental software workflow is identical between the subject and predicate device in that CT DICOM images are triaged, segmentation of the image occurs, landmarks are placed on the 3D reconstructed bone model, planning/approval by the surgeon and creation of the guide and bone model. The workflow remains unchanged from the predicate device K232425.
- **Software Output:** The AI/ML model used in the Segmentation step within the CT Reconstruction internal software application was updated by retraining the model with production grade scapula and humerus CT segmentations where as in the predicate the AI/ML model was trained with production grade scapula scans and the humerus scans were exploratory quality used to develop the model. The Landmarking step within the internal software application was updated with option to select additional configurable landmarks, and like the predicate uses existing landmarks to determine the reference coordinate systems to provide native bone information.

Summary of Performance Data (Nonclinical and/or Clinical):

The following performance data was provided in support of the substantial equivalence determination:

Device Performance Testing:

Verification and Validation Testing for Signature™ ONE System was conducted with the following aspects:

- Performance Tests: Performance tests documented to ensure the performance of the implemented features and verify related design inputs.
- Engineering Analysis: Analysis documented to ensure the performance of the implemented features and verify related design inputs.
- Usability Engineering: Performance of the system in regards to human factors engineering. This remains unchanged and applicable from the predicate K232425.
- Validation: Validation performed to validate related user needs, intended use and safety and effectiveness. This remains unchanged and applicable from the predicate K232425.

Software Verification and Validation Testing

Software tests were conducted to satisfy the Enhanced Level of Documentation per requirements of Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff issued on June 14, 2023 and IEC 62304 (Medical Device Software- Software Life Cycle Processes). The testing demonstrates that the Signature™ ONE System does not raise any different questions of safety and effectiveness as compared to the predicate devices.

Substantial Equivalence Conclusion

The proposed and predicate device have the same Intended Use and Indications for Use, principle of operation, Guides/Bone Models, similar technological characteristics and same software workflow. The new AI/ML model for automatic segmentation is used in the same way as the predicate device. The additional configurable landmarks in the Landmarking step does not change the existing landmarking application and the overall software workflow remains the same as the predicate device. In summary, any differences between the devices does not raise different questions of safety and effectiveness and the proposed device is at least as safe and effective as the legally marketed predicate device.