June 4, 2026

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

Re: K261510
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
Dated: May 6, 2026
Received: May 7, 2026

Dear Camilo Aranguren:

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 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,

FARZANA SHARMIN -S

Farzana Sharmin, Ph.D.
Assistant Director
DHT6C: Division of Joint Arthroplasty 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)*
K261510

Device Name
Signature™ ONE System

Indications for Use *(Describe)*
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, and OsseoFit® Stemless Shoulder System.

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

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

510(k) #: K261510

Contact Details

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 3058165696
Applicant Contact	Mr. Camilo Aranguren
Applicant Contact Email	Camilo.Aranguren@zimmerbiomet.com

Device Name

Device Trade Name	Signature™ ONE System
Common Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Name	Shoulder Arthroplasty Implantation System
Regulation Number	888.3660
Product Code(s)	QHE, HSD, KWT, KWS, MBF, PHX

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name	Product Code
K260104	Signature™ ONE System	QHE

Device Description Summary

The Signature™ ONE System is developed to assist in pre-operative planning of the glenoid and humeral components in skeletally mature individuals for Total Shoulder Arthroplasty (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. Both anatomic and reverse (TSA and RSA respectively) approaches are supported.

The 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 pre-operative planning software is used by the surgeon to review, modify and approve the pre-operative plan of the shoulder joint prepared by a internal operator according to surgeon preferences. The glenoid and humerus implant type, as well as the size, position and orientation of their components can be visualized and adjusted.

The system uses a Non-Device Medical Device Data System (MDDS) 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.

Intended Use/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, and OsseoFit® Stemless Shoulder System.

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

Indications for Use Comparison

The indications for use was updated to include additional shoulder implant compatibility to the Signature ONE System. The intended use remains same to assist in pre-operative planning and/or intraoperative guiding of surgical instruments for shoulder replacement surgical procedures (anatomic and reverse).

The existing predicate tools and features in the pre-op planning software such as implant components selection as well as its position, orientation and size selection remains unchanged. The overall software workflow remains the same as the predicate device and no critical tasks were added or updated.

Technical Comparison

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

• Indications for Use/Intended Use: The subject and predicate device are indicated to assist in pre-operative planning and/or intraoperative guiding of surgical instruments for shoulder replacement surgical procedures (anatomic and reverse). Overall, the Intended Use remains unchanged since the predicate device and the Indication for Use was updated to reflect the new compatible implant systems.
• Principle of Operation: The subject and predicate devices both utilize pre-operative images, and intraoperative guidance of instruments. The Principle of Operation remains unchanged.
• 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.
• Technological Characteristics: The technological characteristics remains unchanged from the predicate device.
• Software User Interface (UI): The software UI includes additional compatible implant components without changing the fundamental technological characteristics for the user. The predicate tools and features used in the software remain unchanged.
• Software Workflow: The workflow remains unchanged.
• Software Output: The software modifications do not alter the fundamental pre-operative technical output of the subject device from the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Gap analysis and verification activities for the release of the upgrades (v2.3) were conducted to support substantial equivalence (SE). There were no critical tasks added or updated and usability remains unchanged from predicate. Software tests were conducted to satisfy the Enhanced Level of Documentation to meet the relevant requirements which demonstrated that the Signature™ ONE System does not raise any new issues of safety and effectiveness as compared to the predicate devices.