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

December 12, 2023

Re: K232425
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: November 15, 2023
Received: November 16, 2023

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 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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2023.12.12 16:22:45 -05'00'

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

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)*
K232425

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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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 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, CANADA H3C 2N6
Establishment Registration Number: 9617840

**Contact Person**:

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

**Preparation Date:**

09 AUG 2023

**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:**

| | | |
|---|---|---|
| K212560 (primary) | Signature™ ONE System | Zimmer CAS |
| K211359 (secondary) | Tornier Perform™ Patient-Matched Primary Reversed Glenoid and BLUEPRINT™ Patient Specific Instrumentation | Tornier, Inc. |

**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 this submission is to introduce new hardware kits for the existing compatible Comprehensive Reverse Augment implants and to include the addition of pre-operative planning of humeral components. A Rotational Guide component will be available as part of these two kits. Modifications have been made to the software applications to accommodate the new guide ordering option. The overall manufacturing process, materials, sterilization methods, have not changed from the previous primary predicate and principal of operation

| | |
|---|---|
| | remains similar. |
| **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.<br><br>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.<br><br>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.<br><br>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.<br><br>The Signature™ ONE System Guides and bone models are intended for single use only. |
| **Differences in Indications for Use:** | The indications for use was updated to include compatibility with implant systems for humerus pre-operative planning that was not present with primary predicate device K212560. |

**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:** Similar to predicate device with new compatibility addition
- **Materials:** Same as predicate device
- **Sterilization:** Same as predicate device
- **Design Features:** The new Rotational Guide component is made available for use with the Comprehensive Reverse Augment workflow from the primary predicate device and provided in two new kits. Modifications have been made to the software applications and the overall workflow from the primary predicate device to incorporate humerus pre-operative planning.

**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.
- Validation: Validation performed to validate related user needs, intended use and safety and effectiveness.

**Software Verification and Validation Testing**

Software tests were conducted to satisfy the Basic 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 new issues of safety and effectiveness as compared to the predicate devices.

**Substantial Equivalence Conclusion**

The proposed and predicate device have the same intended use and similar indications for use, technological characteristics and principle of operation with the difference due to compatibility addition of pre-operative planning of humeral components and new guide. The new Rotational Guide in proposed device is similar to guides provided in primary predicate device to assist in intra-operative guiding of surgical instruments. In summary, any differences between the subject and predicate devices do not raise different questions of safety and effectiveness and the proposed device is at least as safe and effective as the legally marketed predicate devices.