



August 30, 2019

Orthosoft, Inc. (d/b/a Zimmer CAS)
Paul Hardy
Regulatory Affairs Senior Specialist
75 Queen St Suite 3300
Montreal, CA H3C 2N6

Re: K192074

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, PHX, KWS, MBF
Dated: August 1, 2019
Received: August 2, 2019

Dear Paul Hardy:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K192074

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 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 and Comprehensive® Reverse Augmented Baseplates.

The Signature™ ONE 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

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 August 12, 2005.

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

Contact Person: Paul Hardy
Regulatory Affairs Sr. Specialist
Telephone: 574-372-6799

Date: August 28, 2019

Subject Device: **Trade Name:** Signature™ ONE System
Common Name: Shoulder Arthroplasty implantation system

Classification Name:

- QHE– Shoulder Arthroplasty implantation system (21 CFR 888.3660)

Additional Product Codes

- KWT- Shoulder joint metal/polymer non-constrained cemented prosthesis
- KWS- Shoulder joint metal/polymer semi-constrained cemented prosthesis
- PHX- Shoulder joint metal/polymer non-constrained cemented prosthesis
- MBF- Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous coated uncemented prosthesis

Predicate Device(s):

K190595

Signature™ ONE Zimmer CAS
System**Purpose and Device
Description:**

The Signature™ ONE System is developed to assist in pre-operative planning of the glenoid component 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) if desired. Both anatomic and reverse (TSA and RSA respectively) approaches are supported.

The Signature ONE Guides and Bone Model are designed and manufactured of polyamide (nylon) using additive manufacturing (selective laser sintering), based on the approved/finalized pre-surgical plan and shipped prior to surgery. The guides and bone models are provide non-sterile and sterilized at the hospital. They are used intra-operatively to assist the surgeon in reproducing the plan. The Signature ONE System surgical technique remains close to the conventional shoulder arthroplasty to allow converting to standard surgical technique at any time if needed during the operation.

The Signature™ ONE System uses the Zimmer Biomet Drive 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.

Modifications have been made to some of the applications to improve the overall workflow; however, the patient specific guides and bone models remain unchanged from the predicate. In addition, modifications have been made to the user interface of the planning application.

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 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 and Comprehensive® Reverse Augmented Baseplates.

The Signature™ ONE 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:** Same as predicate device
- **Indications for Use:** Same as predicate device
- **Materials:** Same as predicate device
- **Design Features:** Modifications have been made to some of the planning applications, but the patient specific guides and bone models remain unchanged.

Summary of Performance Data (Nonclinical and/or Clinical)

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

-Addition of a landmark to the Signature ONE Planner to display the location of the deepest glenoid point

- A feature is added to the Signature ONE Planner to display the medial/lateral translation between the backside on the implant and a reference landmark located on the most lateral point of the glenoid

- A feature is added to the Signature ONE Planner to display the percentage of contact between the selected implant and the glenoid surface

All of the test steps passed successfully.

**Substantial Equivalence
Conclusion**

The proposed and predicate device have the same intended use and the same principles of operation. The modifications to the proposed device do not alter the Indications for Use or the fundamental technology of the predicate device, or introduce any new technology. In sum, any differences between the devices do not raise new questions of safety and effectiveness and the proposed device is at least as safe and effective as the legally marketed predicate device.