June 05, 2019

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

Re: K190595
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
Dated: March 6, 2019
Received: March 7, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190595

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.

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:

June 5, 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):

Manufacturer	Device Name	510(k) Number
Zimmer CAS **Primary*	Zimmer PSI Shoulder	K150730
Biomet	Signature Personalized Patient Care System-Glenoid Guide System	K130126
Zimmer CAS **Reference Device*	CAS PSI Knee System	K131409

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.

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.

Differences in Indications for Use

The proposed device offers options specific to the compatible implant components that are not present in the primary predicate device

Summary of Technological Characteristics:

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

- The proposed and predicate device are intended to assist in pre-operative planning and/or intraoperative guiding of surgical instruments for shoulder replacement surgical procedures
- The proposed and predicate device both utilize preoperative images, intraoperative guidance of instruments, and assistance of glenoid component placement
- The proposed 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 proposed and predicate device utilize internal manufacturing software applications and a planning application that the surgeon interacts with to review, modify and approve the plan

Summary of Performance Data (Nonclinical and/or Clinical)

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

Biocompatibility Testing

The biocompatibility evaluation for Signature™ ONE System was conducted in accordance with ISO 10993. The evaluation reveals that the Signature™ ONE System device meets biocompatibility requirements.

Sterilization and Shelf-Life

This analysis was conducted to ensure that the cleaning and sterilization instructions for the Signature™ ONE System parts respect the acceptable residual levels that should be achieved by the cleaning and sterilization method, as required by the applicable standards. Testing was also conducted to ensure the acceptance criteria was met of the guides keeping their dimensional integrity throughout their shelf life of 6 months.

Device Performance Testing

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

- Physical/Performance Tests- to ensure the performance of the implemented features and verify related design inputs
- Engineering Analysis- to ensure the performance of the implemented features and verify related design inputs
- Usability Engineering- addressed user interactions with the Signature™ ONE System
- Validation Lab- performed to validate that using the Signature™ ONE System is safe and effective and that the performances of the Signature™ ONE System are acceptable under full simulated use on cadaveric specimens

Software Verification and Validation Testing

Software tests were conducted to satisfy the requirements of the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and IEC 62304 (Medical Device Software- Life Cycle Process). The software is considered a "moderate" level of concern, a malfunction in the device could lead to a minor injury. The testing demonstrates that the Signature™ ONE System does not raise any new issues of safety and effectiveness as compared to the predicate device(s).

Substantial Equivalence Conclusion

The proposed and predicate device(s) have the same intended use and similar technological characteristics and the same principles of operation. The proposed device offers options specific to the compatible implant components that are not present in the predicate device as well as the option for the user to end the preoperative workflow after planning without ordering guides. In addition, the proposed device pin guide provides a larger contact surface than found on the predicate device. 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(s).