December 28, 2017

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

Re: K171269
Trade/Device Name: X-PSI Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, OOG, MBH, LLZ
Dated: November 17, 2017
Received: November 20, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K171269

Device Name
X-PSI Knee System

Indications for Use *(Describe)*
The X-PSI Knee System is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of provided patient radiological images and 3-D reconstructed bones with identifiable placement anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. The X-PSI Knee system is indicated for patients without severe bone deformities, such as a HKA greater than 15° or deformities due to prior fracture of the distal femur or proximal tibia.

The X-PSI Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen® CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona® CR, Persona PS, Vanguard® CR and Vanguard PS.

The patient specific guide components 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Zimmer Biomet® X-PSI Knee System 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 Zimmer Biomet ® X-PSI Knee 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, Quebec, CANADA H3C 2N6
Establishment Registration Number: 9617840

Contact Person: Paul Hardy
Zimmer Biomet
574-372-6799

Date: December 27, 2017

Subject Device: Trade Name: Zimmer Biomet® X-PSI Knee System
Common Name: Surgical Knee Guide

Product Codes: OOG, JWH, MBH, LLZ

Classification Name:

- Knee Joint Patello/Femorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis / 21 CFR § 888.3560 / Product Code JWH
- Knee Joint Patello/Femorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis / 21 CFR § 888.3560 / Product Code OOG
- Prosthesis. Knee, Patello/Femorotibial. Semi-Constrained, uncemented. Porous. Coated, Polymer/Metal / MBl-, Knee Joint Patello/Femorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis / 21 CFR § 888.3565/ Product Code MBH
- Picture Archiving and Communications System/ 21 CFR § 892.2050 / Product Code LLZ

Predicate Device(s):

Manufacturer	Device	510(k) Number	Type
Zimmer CAS	CAS PSI Knee System	K131409	Predicate
ONEFITMedical	Knee EOS	K161828	Reference

Zimmer Biomet® X-PSI Knee System 510(k) Summary

Device Description:
The present Zimmer Biomet® X-PSI Knee System is an instrumentation system that includes customized surgical guides to mate each patient's bony and articular surface topographies to reference the location and orientation of the implant system's instruments which in turns sets the position and alignment of the femoral and tibial implant components.

It involves the following:

- A **CAS X-PSI Knee Software Suite** used in preparation for the surgery to sequentially construct 3-D surface models of each patient's knee joint bony structures and articular surfaces from the patient's X-Ray images, plan the location and orientation of the knee replacement implant components upon the patient's model, and create the corresponding specification models for the patient specific surgical guides (PSI Guides) with surfaces and elements to uniquely fit each patient topographical features and set or reference the placement of the implant system components per the plan,
- The **Zimmer Biomet ® X-PSI Guides** (**also called jigs**) that are manufactured per the above models and plan, for intra-operative and single use, which include one to set the placement of the distal femoral cut guides which set the resection depth, the varus/valgus and the flexion of the distal cut and one to set the placement of the tibial cut guides which set the resection depth, the varus/valgus, and the posterior slope of the proximal cut.
- Each patient's **Zimmer Biomet ® 3-D Bone Models** (femur and tibia components) that are fabricated and provided along with the PSI Guides for use intra-operatively to provide the surgeon with an intra-operative visual reference of the planned location of the PSI Guides in order to help guide their locations on the patient's actual joint,
- **Zimmer Biomet ® X-PSI Reusable Surgical Instrumentations** are provided both sterile and non-sterile and are reusable for intra-operative use, which include femoral stylus, and femoral and tibial cut block instrumentations to allow setting the resection level and performing the bone cuts as defined by the PSI Guides.
- **Fixation Pins** are accessories for use of the guides, these accessories are Class I devices under the classification "Orthopedic manual surgical instrument (21 CFR § 888.4540)''.

The Zimmer Biomet® X-PSI Knee System is compatible for use with the following class II Zimmer Biomet Nexgen, Persona and Vanguard total knee replacement implant systems:

- NexGen® family: NexGen CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender
- Persona® family: Persona CR, Persona PS
- Vanguard® family: Vanguard CR, Vanguard PS

Finally, the following accessories are used for the acquisition of the x-ray images:

- X-Ray Marker 3D Zimmer Biomet ® X-PSI (re-usable)
- X-Ray Calibration Straps, Short and Long (single-use)

Zimmer Biomet® X-PSI Knee System 510(k) Summary

These accessories are class I device under the classifications "Radiologic quality assurance instrument (21 CFR § 892.1940)" and "Radiographic film marking system (21 CFR § 892.1640)".

Indications for Use:
The Zimmer Biomet® X-PSI Knee System is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of provided patient radiological images and 3-D reconstructed bones with identifiable placement anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. The X-PSI Knee system is indicated for patients without severe bone deformities, such as a HKA greater than 15° or deformities due to prior fracture of the distal femur or proximal tibia.

The Zimmer Biomet® X-PSI Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen® CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPSFlex Gender, Persona® CR, Persona PS, Vanguard® CR and Vanguard PS.

The patient specific guide components are intended for single-use only.

Summary of Technological Characteristics:

- While the CAS PSI Knee System uses MRI DICOM as an input, the Zimmer Biomet® XPSI Knee System utilizes x-ray DICOM as an input as does the Knee EOS System.
- Both the CAS PSI Knee System and the Zimmer Biomet ® X-PSI Knee System utilize the same software suites for triage, reconstruction, landmark acquisition, planning, guide creation, and bone model creation.
- The Guides are substantially equivalent, however the Zimmer Biomet® X-PSI Knee System guides utilize a different method for attachment to the knee joint than that used in the CAS PSI Knee System.
- The guides and bone models are manufactured using a 3-D printing method, Selective Laser Sintering (SLS).

Summary of Performance Data:
(Nonclinical and/or Clinical)
Four different types of non-clinical and/or clinical tests were conducted to verify and validate the performance of the system and assess that no new safety and efficacy issues were raised in the device.

- **Software System Tests**: They were performed to ensure that no hazardous anomalies were present in the system software components. They consisted of testing software features and functionalities in correspondence to software design requirements.
- **Guide Mechanical Resistance Tests:** Tests were performed to verify the mechanical

Zimmer Biomet® X-PSI Knee System 510(k) Summary

performance of the guides including resistance to use or drop breakage, debris generation, aging stability, sterilization, and extreme shipping conditions.

- **Full System Validation Tests:** Full use simulations tests using cadaver specimens and/or bone models were performed by multiple surgeons in multiple settings to verify and validate the overall system performance in terms of system usage and instrument ergonomics. The results demonstrated that the X-PSI Knee System is substantially equivalent in cut accuracy with regards to femoral and tibial frontal and sagittal angles, as well as femoral rotation and resection depth.
- **Non-Significant Risk Clinical Study:** A clinical study was performed to evaluate proper positioning of the Zimmer Biomet® X-PSI Knee guides. This study measured the resulting frontal Hip-Knee-Ankle (HKA) alignment angle versus the surgically planned HKA alignment angle. The results demonstrated satisfactory performance per the intended use.

Substantial Equivalence Conclusion:

In summary, the proposed Zimmer Biomet® X-PSI Knee System is substantially equivalent to the CAS PSI Knee System predicate, as well as the kneeEOS reference in regards to X-Ray imaging and reconstruction with the same intended use and similar technology. Design verification and validation tests, including performance and clinical tests, demonstrated the substantial equivalence of the system.