DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Zimmer
Mr. Christopher McLean
Quality & Regulatory Affairs Associate Director
75 Queen Street, Suite 3300
Montreal, Quebec H3C 2N6
Canada

June 16, 2015

Re: K150730
Trade/Device Name: Zimmer PSI Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, KWS, PHX
Dated: March 18, 2015
Received: March 20, 2015

Dear Mr. McLean:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K150730

Device Name
Zimmer PSI Shoulder System

Indications for Use *(Describe)*

The Zimmer® PSI Shoulder 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 Zimmer® PSI Shoulder is to be used with the glenoid components of the following shoulder implant systems in accordance with their indications and contraindications: Zimmer® Bigliani/Flatow® Complete Shoulder Solution, Zimmer® Trabecular Metal™ Glenoid, and Zimmer® Trabecular Metal™ Reverse Shoulder.

The Zimmer® PSI Shoulder instrument guides and bone model 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 OF SAFETY AND EFFECTIVENESS
ZIMMER PSI SHOULDER SYSTEM

Applicant: Zimmer CAS
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Canada, H3C 2N6
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Contact Person: Christopher McLean

Date Summary Prepared: March 18, 2015

Device Trade Name: Zimmer PSI Shoulder System (previously called CAS PSI Shoulder)

Product Code / Device Name, Regulation Classification Number (Name):

1) Code **KWS** / prosthesis, shoulder, semi-constrained, metal/polymer cemented, under **21 CFR § 888.3660** (Shoulder joint metal/polymer semi-constrained cemented prosthesis)
2) Code **PHX** / shoulder prosthesis, reverse configuration, under regulation **21 CFR § 888.3660** (Shoulder joint metal/polymer semi-constrained cemented prosthesis)
3) Code **KWT** / prosthesis, shoulder, non-constrained, metal/polymer cemented, under regulation **21 CFR § 888.3650** (Shoulder joint metal/polymer non-constrained cemented prosthesis)

Predicate Devices: CAS PSI Shoulder System, from Zimmer CAS, 510(k) # K131129, cleared Aug. 20th, 2013

Device Description:

The Zimmer PSI Shoulder System is an orthopedic instrument system indicated to assist in the positioning of shoulder replacement components. It involves surgical planning software used pre-operatively, and surgical instrument components that include patient specific guides to precisely align and position the implant components intra-operatively relative to each patient's anatomical features per the surgical plan. The surgical planning software allows the review of patient joint models determined from radiological images upon which the surgical placement of the implant components is adjusted per anatomical landmarks and the applicable shoulder arthroplasty surgical techniques. The patient specific guides are fabricated per the patient models to fit each patient's anatomy with features that set the relative placement of the implant components per the surgical plan. The system is compatible with given implant systems per its indications for use.

Zimmer PSI Shoulder 510(k)

Indications for Use / Intended Use:
The Zimmer® PSI Shoulder 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 Zimmer® PSI Shoulder is to be used with the glenoid components of the following shoulder implant systems in accordance with their indications and contraindications: Zimmer® *Bigliani/Flatow*® Complete Shoulder Solution, Zimmer® *Trabecular Metal*™ Glenoid, and Zimmer® *Trabecular Metal*™ Reverse Shoulder.
The Zimmer® PSI Shoulder instrument guides and bone model are intended for single use only.

Technological Comparisons to the Predicates:
The change is to extend the compatibility for use to assist in the placement of the glenoid components of two additional shoulder implant systems: the Zimmer® *Bigliani/Flatow*® Complete Shoulder Solution and the Zimmer® *Trabecular Metal*™ Glenoid. The predicate was compatible with the Zimmer® *Trabecular Metal*™ Reverse Shoulder implant system.

The system is composed of the following two main components involving the same main technology and methods as in the predicate:

- Software to perform the planning per the patient's CT scans and in accordance with the given implant system,
- Hardware that includes surgical Guides (or Jigs as called in the predicate) adjusted to fit the individual patients' anatomy and transfer the pre-operative plan, and a bone model of the patient's glenoid to provide the surgeon with an intra-operative visual reference of the planned location of the Guides.

The predicate system software was modified and additional guides were added to the current ones to accommodate the added implant techniques. This included:

- Implementing models in the software of the new implant components to allow the related planning steps as in the predicate,
- Adding two new sizes, 20 & 21 mm, of Pin Guides and Reamer Guides to the current range of sizes,
- Adding a new non-cannulated type of Reamer Guide,
- Implementing in the planning software the placement of the drill guide instrument of the added implant systems.

In addition other general improvement unrelated to the above compatibility changes were also included: automatic generation of the pre-operative report, implementation of a new DICOM header reader, and improvements in the slice distance calculation and thresholding algorithms.

Performance Data:
Three different types of non-clinical tests or analyses were conducted to verify and validate that the performance of the system was maintained from the predicate and that no new safety and efficacy issues were raised in the device:

- **Software System Tests**: These were performed to verify that the software changes function as required and that they did not impact the existing software functions.
- **Full System Validation Tests:** Full use simulations tests using cadaver specimens or sawbones were performed by multiple surgeons to verify and validate the overall system performance in terms of system usage, instrument ergonomics, and accuracy when used with the added implant systems. The results demonstrated satisfactory performance per the intended use as in the predicate.
- **Predicate Component Test Validity Analysis:** The predicate hardware component tests were reviewed to assess that they were still applicable for the modifications to the PSI guides and to confirm their continued adequacy in terms of sterilization by the user, biocompatibility, and mechanical safety tests including drop resistance, use resistance, stability, and packaging effects.

Conclusion:
The information and data provided in the 510(k) Premarket Notification established that the Zimmer PSI Shoulder System is substantially equivalent to the predicate.