March 17, 2020

Zimmer, Inc.
Pankti Shah
Regulatory Affairs Specialist
1800 W. Center Street
Warsaw, IN 46580

Re: K200151
Trade/Device Name: Persona Partial Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: January 21, 2020
Received: January 22, 2020

Dear Pankti Shah:

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 Ting Song
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200151

Device Name
Persona Partial Knee System

Indications for Use *(Describe)*
Indications for Persona Partial Knee System:

The Persona Partial Knee system is limited to the medial tibiofemoral compartment of the knee intended for patients with painful and/or disabling knee joints due to the following indications:

- Noninflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, avascular necrosis;
- traumatic arthritis;
- previous tibial condyle or plateau fractures with loss of anatomy or function;
- varus deformities; and
- revision of the articular surface of a previously implanted Persona Partial Knee System providing that the tibial plate locking mechanism is not compromised and the femoral and tibial plate components remain well fixed and undamaged.

The Persona Partial Knee System is a single use implant intended for implantation with bone cement.

Indications for combined Persona Partial Knee System and Zimmer Gender Solutions Patello-Femoral Joint (PFJ):

- Osteoarthritis, traumatic arthritis, polyarthritis, and/or severe chondrocalcinosis of the patellofemoral joint.
- The salvage of previously failed surgical attempts (e.g., arthroscopy, lateral release, cartilage transplantation).
- History of patellar dislocation or patella fracture.
- Dysplasia-induced degeneration.

These indications will be used for the combined medial unicompartmental and patello-femoral implant device, whereby a single condyle and patello-femoral regions have been affected by one or more of these conditions.

Combined Persona Partial Knee System and Zimmer Gender Solutions Patello-Femoral Joint (PFJ) implants are intended for implantation with bone cement.

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 Persona Partial 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:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

Contact Person:

Pankti Shah
Regulatory Affairs Specialist
Telephone: 574-371-9830

Date:

21 January 2020

Subject Device:

Trade Name: Persona® Partial Knee System

Common Name: Knee Prosthesis

Classification Name:

- HSX– Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer (21 CFR 888.3520)

Predicate Device(s):

Device	510(k) Number	Manufacturer
Persona Partial Knee System	K161592	Biomet, Inc.

Purpose and Device Description:

The Persona Partial Knee (PPK) system is a partial knee replacement system for the medial compartment of the knee and is modular in design consisting of three implant components:

- Unicondylar Cobalt-Chromium-Molybdenum (Co-Cr-Mo) alloy Femoral components
- Unicondylar Vivacit-E ® Vitamin-E Highly Crosslinked Polyethylene (VEHXPE) Articular surfaces
- Unicondylar Titanium (Ti-6Al-4V) alloy Tibial components

The Persona Partial Knee System includes surgical instrumentation that facilitate implantation of the above described implant components.

The purpose of this submission is to 1) introduce an alternate surgical technique for proximal tibial resection, accomplished via the introduction of new tibial cut guides and recutters; 2) introduce a new peg drill for preparation of tibial bone; all of which are intended to be used specifically with the Persona Partial Knee system and 3) reclassify the existing tibial cut guides, recutters and the peg drill used with various partial knee systems as Class II devices.

The new instruments do not change the intended use or fundamental scientific technology of the Persona Partial Knee System components.

Intended Use and Indications for Use:

The Persona Partial Knee System is intended for use in partial knee arthroplasty. Instrumentation is intended to facilitate implantation of the Persona Partial Knee implants.

Indications for Use for the Persona Partial Knee System are as follows:

The Persona Partial Knee system is limited to the medial tibiofemoral compartment of the knee intended for patients with painful and/or disabling knee joints due to the following indications:

- Noninflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, avascular necrosis;
- traumatic arthritis;
- previous tibial condyle or plateau fractures with loss of anatomy or function;
- varus deformities; and
- revision of the articular surface of a previously implanted Persona Partial Knee System providing that the tibial plate locking mechanism is not compromised and the femoral and tibial plate components remain well fixed and undamaged.

The Persona Partial Knee System is a single use implant intended for implantation with bone cement.

Indications for combined Persona Partial Knee System and Zimmer Gender Solutions Patello-Femoral Joint (PFJ):

- Osteoarthritis, traumatic arthritis, polyarthritis, and/or severe chondrocalcinosis of the patellofemoral joint.
- The salvage of previously failed surgical attempts (e.g., arthroscopy, lateral release, cartilage transplantation).
- History of patellar dislocation or patella fracture.
- Dysplasia-induced degeneration.

These indications will be used for the combined medial unicompartmental and patello-femoral implant device, whereby a single condyle and patello-femoral regions have been affected by one or more of these conditions.

Combined Persona Partial Knee System and Zimmer Gender Solutions Patello-Femoral Joint (PFJ) implants are intended for implantation with bone cement.

Summary of Technological Characteristics:

The subject instruments do not change the intended use or the fundamental scientific technology of the existing instruments.

- **Intended Use:** Identical to the predicate
- **System Indications for Use:** Identical to the predicate
- **Materials:** Similar to the predicate
  - PPK Tibial Cut guides and Recutters: Stainless Steel (17-4 PH SST), Titanium Nitride (TiN) Coating
  - PPK Tibial Peg Drill: Stainless Steel (17-4 PH SST)
- **Design Features:** Similar to the predicate
  - The subject tibial cut guides and recutters have modified pin hole location and an open landing to allow for a non-captured sagittal cut. These cut guides and recutters have a titanium nitride coating, to allow for visual differentiation from

the previously marketed tibial cut guides and recutters.
    - The subject tibial peg drill is designed such that it has 2mm reduced from the shaft of the drill tip. This peg drill shaft has three engraved grooves and has "PPK" etched to allow for visual differentiation from the previously marketed tibial peg drill.

- **Sterilization & Packaging:** Identical to the predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
    - Cut guide and recutter simulated use verification
    - Tibial plateau strains evaluation
    - Cadaveric design validation
    - Functional relationship analyses
    - Biocompatibility assessment

- **Clinical Tests:**
    - Clinical data was not deemed necessary to establish substantial equivalence between the subject and predicate devices.

Substantial Equivalence Conclusion

The subject devices have the same intended use and indications for use as the predicate devices. The subject device has similar technological characteristics to the predicates, thus the non-clinical performance data and analyses demonstrate that:

- any differences 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 devices.