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

Biomet, Inc.
Ms. Nicole Meredith
Regulatory Affairs Project Manager
56 East Bell Drive
PO Box 587
Warsaw, Indiana 46581

November 3, 2016

Re: K161592
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: October 4, 2016
Received: October 6, 2016

Dear Ms. Meredith:

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" (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.

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)*
K161592

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 Systemknee surgeries 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K161592

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:
Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact:
Nicole J. Meredith
Regulatory Affairs Project Manager
574-377-3718

Date:
November 1, 2016

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)

Legally marketed devices to which substantial equivalence is claimed:

- Miller/Galante Unicompartmental Knee (K010685/K942263/K880155)
- Zimmer Unicompartmental Knee System (K122529/K033363)
- Repicci II Unicondylar Knee (K971938)
- Allegretto Unicompartmental Knee (K011954)
- Zimmer Persona Personalized Knee System (K113369/K121771/K150090) – reference device for A/P medial dimensions, MR conditional labeling, and materials
- Vanguard XP Knee System (K141407/K122160) – reference device for implant-specific accessories/instruments

Device Description

The Persona Partial Knee (PPK) System is a partial knee replacement for the medial compartment of the knee and is modular in design consisting of three components: a unicondylar cobalt-chromium-molybdenum (Co-Cr-Mo) alloy femoral component, a unicondylar titanium (Ti-6Al-4V) alloy tibial tray, and a unicondylar articular surface manufactured using the previously cleared Vivacit-E ® Vitamin-E Highly Crosslinked Polyethylene (VEHXPE).

The Persona Partial Knee System is compatible with the following devices:

- Zimmer Patellofemoral Joint Prosthesis (K070695)

Intended Use and Indications for Use
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.

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

- **Intended Use:** The Persona Partial Knee System and predicate devices have the same intended use; for replacement of one compartment of the knee. The predicate devices are intended for the medial or lateral compartment. The Persona Partial Knee System is intended for the medial compartment only. The Persona Partial Knee System and predicate devices are intended for cemented use.
- **Materials:**
    - The Persona Partial Knee femoral components are composed of the same material (Co-Cr-Mo alloy) as the Repicci II Unicondylar Knee (K971938) predicate

and the Zimmer Persona Personalized Knee System component (K113369) reference device.
    - The Personal Partial Knee articular surfaces are manufactured from the same material (Vivacit-E Vitamin E Highly Crosslinked Polyethylene) as the predicate Zimmer Unicompartmental Knee System (K122529) and in the Zimmer Persona Personalized Knee System reference device (K150090 and K121771).
    - The Personal Partial Knee tibial components are composed the same material (Ti-6Al-4V alloy) as that used in the Miller/Galante Unicompartmental Knee (K010685) and the Zimmer Unicompartmental Knee System (K033363) predicates, and the Zimmer Persona Personalized Knee System (K113369) reference device.
- **Design Features:** The Persona Partial Knee System incorporates similar design features as the predicate devices.
- **Sterilization:** The Persona Partial Knee System implants and predicate devices are provided sterile for single-use.

Summary of Performance Data

Results from mechanical tests and engineering analyses demonstrate the proposed PPK components are substantially equivalent to the predicate devices. No animal or clinical testing was required to support substantial equivalence. A description of the non-clinical tests and analyses performed are listed below.

- Femoral Component
    - Cantilever fatigue per internal test method
    - 3-Point Bending Fatigue per internal test method
- Articular Surfaces
    - Contact area per ASTM F2083
    - Constraint per ASTM F2083 and ASTM F1223
    - Posterior Crush and Lift Off per internal test method
    - Wear per engineering analysis
    - Static locking mechanism strength per internal test method
- Tibial Components
    - 3-Point bending fatigue per internal test method
- System Compatibility
    - Patellar component and PFJ compatibility per engineering analysis
    - MR compatibility per engineering analysis
- Bacterial Endotoxin Testing (BET)
    - BET demonstrated the pyrogen limit specifications have been met

Substantial Equivalence Conclusion

The Persona Partial Knee System has the same or similar intended use, materials, and design characteristics as the predicate devices. Performance data and analyses demonstrate the device is as safe and effective and is substantially equivalent to the legally marketed predicate devices.