June 4, 2019

Zimmer Inc.
Charles Neitzel
Senior Regulatory Affairs Specialist
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K190068
Trade/Device Name: Vanguard XP 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, MBH, OIY, MBV
Dated: May 7, 2019
Received: May 8, 2019

Dear Charles Neitzel:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

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)*
K190068

Device Name
Vanguard XP Knee System

Indications for Use *(Describe)*

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous total joint replacement procedure.

Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok) femoral components, tibial tray components and all polyethylene patellar components are indicated for cemented application 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.

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zimmer

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 Vanguard XP 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

Contact Person:

Charles Neitzel
Senior Specialist, Regulatory Affairs
Telephone: (262) 716-3243
Fax: (574) 372-4605

Date:

January 11, 2019

Trade Name:

Vanguard XP Knee System

Common Name:

Knee Bearing

Classification Names and References:

- JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)
- MBH - Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Uncemented, Porous Coated, Polymer/Metal/Polymer (21 CFR 888.3565)
- OIY – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive (21 CFR 888.3560)
- MBV – Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uhmwpe, Pegged, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)

Classification Panel:

Orthopedics/87

Predicate Device(s):

<u>Design Predicates:</u>

- Vanguard XP Knee System, manufactured by Biomet, K122160, cleared on 03/20/2013
- Vanguard XP Knee System, manufactured by Biomet, K132873, cleared on 12/11/2013
- Vanguard XP Femoral Component (Gen II)/Vanguard XP Femoral Trial, manufactured by Biomet, K141407, cleared on 10/27/2014

- Vanguard XP Knee System, manufactured by Biomet, K153657, cleared 05/10/2016

Material Predicate:

- Persona® Personalized Knee System, manufactured by Zimmer, K121771, cleared 11/07/2012
- Persona® Personalized Knee System, manufactured by Zimmer, K150090, cleared 05/20/2015

Purpose and Device Description:

The purpose of this subject 510(k) is to introduce a modification to the tibial bearings within the Vanguard XP Knee System. There are no changes to the other components within the system.

The Vanguard XP Knee System is a total knee replacement system that consists of a femoral component composed of cobalt-chromium-molybdenum (Co-Cr-Mo), two styles of tibial trays manufactured out of Co-Cr-Mo (with locking bar), and dual bearings machined of Vivacit-E Vitamin-E Highly Crosslinked Polyethylene (VEHXPE). Biomet patellae can be used with the Vanguard XP Knee System. The subject Vanguard XP tibial components are available with a porous plasma spray (PPS®) of titanium alloy powder for uncemented or cemented fixation or with Biomet's Interlok coarse blasted finish for cemented fixation only. The Vanguard XP Knee System offers the flexibility to retain the ACL and PCL ligaments, retain just the PCL ligament and accommodate an intact, partially functioning PCL within a single system.

Intended Use / Indications for Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous total joint replacement procedure.

Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok) femoral components, tibial tray components

and all polyethylene patellar components are indicated for cemented application only.

Summary of Technological Characteristics:

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

- **Intended Use:** Identical to the predicates
- **Indications for Use:** Similar to the Vanguard XP Knee System predicates
- **Materials:** Identical to the Persona Personalized Knee System predicates
- **Design Features:** Similar to the Vanguard XP Knee System predicates
- **Sterilization:** Identical to the Persona Personalized Knee System predicates

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  Engineering analysis was conducted to demonstrate that the modifications did not adversely affect safety and efficacy, and to demonstrate substantial equivalence to the predicate components. The test reports are listed below:
  - Vivacit-E material characteristics presented in MAF-1868
  - Material and dimensional comparison of Vivacit-E to E1 tibial bearings
  - Evaluation of stress in manufacturing slots of Vivacit-E tibial bearings using finite element analysis
  - Laser etching of Vanguard XP Vivacit-E material
  - Magnetic resonance imaging (MRI) compatibility
  - Testing to establish product non-pyrogenicity

- **Clinical Tests:**
  - Clinical data was not deemed necessary for the subject device.

Substantial Equivalence Conclusion

The subject device has the same intended use and similar indications for use as the Vanguard XP Knee System predicate devices. The subject device has similar technological characteristics to the predicates, and the 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.