DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 10, 2016

Biomet, Incorporated
Ms. Julie Gantenberg
Senior Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K153657
Trade/Device Name: Vanguard XP Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, OIY, JWH, MBV
Dated: April 12, 2016
Received: April 14, 2016

Dear Ms. Gantenberg:

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 Parts 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)*

K153657

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. Regenerex components* are intended only for uncemented biologic fixation application.

*Where Available

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.

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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: Biomet, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Phone Number: (574) 267-6639
Fax Number: (574) 372-4710

Establishment Registration Number: 1825034

Contact: Julie B. Gantenberg, M.S., RAC
Regulatory Affairs Project Manager

Date: April 27, 2016

Subject Device: Trade Name: Vanguard XP Knee System
Common Name: Knee Prosthesis

Product Code-Classification Name:

- MBH - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (21 CFR§888.3565)
- JWH - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3560)
- MBV - Knee joint patellofemorotibial semi-constrained UHMWPE pegged uncemented polymer/metal/polymer (21 CFR §888.3560)
- OIY - Knee joint patellofemorotibial polymer +Additive/metal/polymer +Additive semi-constrained cemented prosthesis (21 CFR §888.3560)

Legally marketed devices to which substantial equivalence is claimed:

- K141407/K132873/K122160 Vanguard XP Knee System
- K113550 Vanguard Knee System
- K904448 Townley Total Knee

Reference Devices for Differential Bearings:

- K094050 ConforMIS iTotal Cruciate Retaining Knee Replacement system - iTotal KRS
- K092201 ADVANCE 913 Medial Pivot Tibial Insert, ADVANCE 913 Medial Pivot Tibial Base

Device Description
The subject Vanguard XP Knee System line extension introduces the 59mm XP-XP Tibial Tray, modifications to corresponding 59mm XP-XP and XP-AS bearings, implant-specific instrumentation, differential bearing (thickness and/or articulation) compatibility and MR conditional labeling for the system.

The Vanguard XP Knee System is a total knee replacement system that consists of a femoral component composed of Co-Cr-Mo, two styles of tibial trays manufactured of Co-Cr-Mo (with locking bar), and dual bearings machined of E1 poly. Biomet patellae can be used with the Vanguard XP Knee System. The subject Vanguard XP-XP tibial components are available in Biomet's Interlok coarse blasted finish for cemented fixation.

Intended Use and Indications for Use
The Vanguard XP Knee System is intended for replacement of a total knee joint and the preservation of the anterior and/or posterior cruciate ligament (ACL/PCL) when used in conjunction with a femoral, tibial and patellar component.

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. Regenerex components* are intended only for uncemented biologic fixation application.

*where available

Summary of Technological Characteristics
The Vanguard XP Knee System is made up of multiple components, including instrumentation, femoral components, several types of bearings and tibial trays.

The technological characteristics of the Vanguard XP Knee System are the same as those of predicate device systems (K141407, K113550 and K904448) in terms of design, material, and principle of operation with the exception of modifications as described in this 510(k). The 59mm XP-XP tray size and corresponding XP bearings are a line addition to the Vanguard XP Knee System and uses the identical manufacturing processes as the predicates. Non-clinical performance testing completed to support substantial equivalence is listed below.

Summary of Performance Data (Nonclinical and/or Clinical):

Non-Clinical Tests:

- Wear
- Contact Area
- Constraint
- Tibiofemoral Stability Locking mechanism test
- Tibial Tray fatigue Test
- Bearing Micromotion Analysis/Cyclic Locking Mechanism Test
- MR Testing

Biomet has performed non-clinical Magnetic Resonance Imaging (MRI) studies on Vanguard Knee implants which are determined to be MR Conditional in accordance to ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Tests included the following:

RF heating- ASTM F2182-11a
Image Distortion- ASTM F2119-07
Magnetically Induced Displacement Force - ASTM 2052-14
CEM43 analysis

Clinical Tests:

- None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

The proposed Vanguard XP devices have the same intended use and indications for use as the predicate devices. Performance test data and analyses demonstrate the device is as safe and effective and is substantially equivalent to the legally marketed predicate devices.