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
Jason Heckaman
Manager, Regulatory Affairs
56 East Bell Drive
Warsaw, Indiana 46581

July 28, 2017

Re: K171054
Trade/Device Name: Biomet Knee Joint Replacement Prostheses
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, HRY, MBV, MBH, OIY
Dated: June 26, 2017
Received: June 27, 2017

Dear Mr. Heckaman:

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,

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)*
K171054

Device Name
Biomet Knee Joint Replacement Prostheses

Indications for Use *(Describe)*

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, and/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 joint replacement procedure.

The Regenerex femoral augments are indicated for use with the Vanguard Total Knee System.

The Regenerex tibial augments are indicated for use with standard and offset Biomet Tibial Trays.

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

Regenerex components are intended only for uncemented biologic fixation application.

The tibial bearings are intended for use with Biomet cemented or uncemented tibial trays.

All-polyethylene patellar components are indicated for cemented 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.

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

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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 Biomet Knee Joint Replacement Prostheses MR Labeling 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: 3003506715

Contact Person:

Jason Heckaman
Manager, Regulatory Affairs
Telephone: (574-371-8313)

Date:

July 27, 2017

Subject Device:

Trade Name: Biomet Knee Joint Replacement Prostheses MR Labeling
Common Name: Knee Prosthesis

Classification Name:

- JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)
- HRY– Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer (21 CFR 888.3530)
- MBV – Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, UHMWPE, Pegged, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)
- MBH – Prosthesis, Knee, Patello/Femorotibial, 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)

Predicate Device(s): **Manufacturer: Biomet, Inc.**

K912245	AGC Revision Knee Prosthesis
K915132	MCK (Maximum Congruent Knee) Knee System
K921182	Ultra High Molecular Weight Polyethylene Component
K960856	Konstruct Patellar Component
K993159	Maxim Knee System
K010212	Offset Tibial Tray
K033489	AGC Total Knee System, Ascent Total Knee System, Maxim Complete Knee System, Maxim Accel Knee System
K040770	Vanguard Patella Components
K042757	Vanguard SSK Knee System
K060525	Vanguard Removable Molded Poly Tibia
K080204	Vanguard Knee System Titanium Femoral Components
K080361	Regenerex Tibial Components
K083782	Regenerex Patella Components
K102125	Patient-Specific Vanguard Femoral Components
K110362	Vanguard Asymmetrical Patellar Component
K113550	Vanguard Complete Knee System
K121149	Vanguard SSK 360 Revision Knee System
K140902	E1 Series A Patellae, Standard 3-Peg, E1 Series A Patellae, Thin 3-Peg, E-1 Series A Patellae, Asymmetrical, 3-Peg
K142933	Biomet Tibial Trays

Summary of Technological Characteristics:

The purpose of this submission is the addition of MR Conditional labeling to the Instructions for Use for the predicate devices. The addition of MR labeling to the subject devices does not impact indications, materials, design features or dimensions, packaging or sterilization. The subject devices are intended for use in total knee arthroplasty.

Indications for Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, and/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 joint replacement procedure.

The Regenerex femoral augments are indicated for use with the Vanguard Total Knee System.

The Regenerex tibial augments are indicated for use with standard and offset Biomet Tibial Trays.

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

Regenerex components are intended only for uncemented biologic fixation application.

The tibial bearings are intended for use with Biomet cemented or uncemented tibial trays.

All-polyethylene patellar components are indicated for cemented use only.

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

Non-Clinical Tests:

- Biomet has performed non-clinical Magnetic Resonance Imaging (MRI) studies on 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
- Testing has been performed to establish product non-pyrogenicity.

- **Clinical Tests:**
  Clinical data was not provided for the subject devices.

Substantial Equivalence Conclusion:

Non-clinical tests provided in this Traditional 510(k) establish the conditional safety and compatibility of the

passive implants in a magnetic resonance (MR) environment. The subject devices are substantially equivalent to the legally marketed predicated devices.