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

February 12, 2015

Biomet, Incorporated
Mr. Jason Heckaman
Regulatory Affairs Project Manager
56 East Bell Drive
Warsaw, Indiana 46581

Re: K143192
Trade/Device Name: Vanguard 360 Revision 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, MBV
Dated: January 13, 2015
Received: January 14, 2015

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" (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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K143192

Device Name: **Vanguard 360 Revision Knee System**

INDICATIONS FOR USE:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, 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) femoral components, tibial tray components and all polyethylene patellar components are indicated for cemented application only. Regenerex and OsseoTi components are intended only for uncemented biologic fixation application.

The Vanguard DA 360 components are not intended for use with the Vanguard PS Open Box Porous Femoral components. **The Vanguard DA 360 components are not approved for sale in the United States or Canada.**

Prescription Use ☒ *(Part 21 CFR 801 Subpart D)*

AND/OR

Over-The-Counter Use ☐ *(21 CFR 801 Subpart C)*

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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 360 Revision 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: Jason Heckaman
Project Manager, Regulatory Affairs
Phone: 574-371-3707
Fax: 574-372-1683

Date: November 5, 2014

Subject Device: Trade Name: Vanguard 360 Revision Knee System
Common Name: Knee Prosthesis

Classification Name:

- JWH – prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer (21 CFR §888.3560)
- MBV–prosthesis, knee, patellofemorotibial, semi-constrained, UHMWPE, Pegged,cemented, polymer/metal/polymer (21 CFR §888.3560)

Legally marketed devices to which substantial equivalence is claimed:

- K093293 Vanguard 360 Revision Knee System

Device Description

The Vanguard 360 Revision Knee System is a total knee replacement system intended for use in primary or revision total knee joint arthroplasty. The system is comprised of a series of femoral and tibial components (bearings and trays) designed to work in conjunction with patella components and optional auxiliary components, including stem extensions, offset adaptors, and tibial and femoral augments. This submission includes a modification to the screw hole location in the 57.5mm Vanguard 360 Posterior Femoral Augments and a subcomponent design and material change in the Vanguard 360 Bowed Stem Extension Trials.

Intended Use and Indications for Use

The subject devices are intended for use in total knee arthroplasty.

Indications for use are as follows:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, 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) femoral components, tibial tray components and all polyethylene patellar components are indicated for cemented application only. Regenerex and OsseoTi components are intended only for uncemented biologic fixation application.

The Vanguard DA 360 components are not intended for use with the Vanguard PS Open Box Porous Femoral components. **The Vanguard DA 360 components are not approved for sale in the United States or Canada.**

Summary of Technological Characteristics
The subject changes include a change in the screw hole location in the subject augments and a change to incorporate a 416 SST cylindrical pin subcomponent in the subject trials.

The subject augments have similar technological characteristics as the predicate. There are no changes to the augment materials, shape, sizes, thicknesses, method of attachment to the femoral components, sterilization method, or shelf life.

The subject bowed stem extension trials also have similar characteristics as the existing trials. There are no changes to the shape or sizes available and the materials of the stem, barrel, and shaft are unchanged (Ti-6Al-4V and 17-4PH SST). Like the existing trials, the subject stem trials will be provided nonsterile.

Performance data has demonstrated that the proposed devices are at least as safe and effective as the legally marketed predicate device.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
  - Tolerance Analysis Report – Vanguard 360 57.5mm Posterior Femoral Augments
  - Vanguard 360 57.5mm Posterior Femoral Augments Fit Evaluation
  - Pull Force Comparison – Bowed Stem Trials
- Clinical Tests
  - Clinical data was not required to establish substantial equivalence between the subject and predicate devices.

Substantial Equivalence Conclusion

Based on the similarities in design, function, intended use and fundamental scientific technology, the devices that are the subject of this submission are similar to the predicate devices and do not introduce any new risks of safety or efficacy. Therefore, Biomet concludes that the subject devices are substantially equivalent to the predicate devices.