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

January 30, 2015

Biomet Incorporated
Mr. Jared Cooper
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K143543
Trade/Device Name: Prelude PF Patellae
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: December 9, 2014
Received: December 15, 2014

Dear Mr. Cooper:

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,

Vincent J. Devlin -S

for
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)*

K143543

Device Name
Prelude PF Patellae

Indications for Use *(Describe)*

The Prelude™ PF Resurfacing Knee System is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

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 Prelude PF Patellae 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: Jared Cooper, PhD
Regulatory Affairs Specialist
Biomet Sports Medicine
Phone: (574) 267-6639
Fax: (574)267-8137

Date: December 9, 2014

Subject Device: Trade Name: Prelude PF Patellae
Common Name: Unicondylar Knee Prosthesis

Classification Name:
- KRR– Prosthesis, Knee, Patello/Femoral, Semi-constrained, Cemented, metal/polymer (21 CFR §888.3540)

Legally marketed devices to which substantial equivalence is claimed:
- K123907 - Prelude PF Knee Resurfacing System
- K040770 – Vanguard Patella Components

Device Description
The patella components are to be used with the existing Prelude PF Knee Resurfacing System. The components manufactured from polyethylene (UHMWPE) conforming to ASTM F-648 with a stainless steel x-ray wire and consist of larger sized patella options.

Intended Use and Indications for Use
The Prelude™ PF Resurfacing Knee System is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

Summary of Technological Characteristics

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

- **Intended Use:** The proposed and predicate Prelude PF Knee Resurfacing System patellae devices have the identical intended use.
- **Indications for Use:** The proposed and predicate Prelude PF Knee Resurfacing System patellae devices have identical indications for use.
- **Materials:** The proposed and predicate Prelude PF Knee Resurfacing System patellae devices are manufactured from UHMWPE conforming to ASTM F648.
- **Design Features:** The proposed and predicate patellae devices incorporate identical design features.
- **Sterilization:** The proposed and predicate Prelude PF Knee Resurfacing System patellae devices are provided sterile via identical sterilization methods for single-use.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
    - Engineering Analysis of the larger patellae demonstrate that the proposed additional sizes to the Prelude PF Knee Resurfacing System patellae do not raise any new risks compared to the predicate Prelude PF Knee Resurfacing System patellae.
- Clinical Tests
    - None

Substantial Equivalence Conclusion

The proposed Prelude PF Knee Resurfacing System patellae have identical intended use, indications for use, and design as the predicate devices. Engineering analysis demonstrates the Prelude PF patellae do not raise any new risks compared to the legally marketed predicate devices.