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

December 23, 2014

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

Re: K142933
Trade/Device Name: Biomet Tibial Trays
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, MBV
Dated: October 27, 2014
Received: October 28, 2014

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 yours,

Lori A. Wiggins -S

for
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): _K142933_____

Device Name: **Biomet Tibial Trays**

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

Regenerex components are intended only for uncemented biologic fixation application.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign Off)
Division of Orthopedic Devices
510(k) Number: K142933

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 Tibial Trays 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: October 30, 2014

Subject Device: Trade Name: Biomet Tibial Trays
Common Name: Knee Prosthesis

Classification Name:

- JWH – prosthesis, knee, patellofemorotibial, semi-constrained, 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)
- 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:

- K915132 MCK (Maximum Congruent Knee) System
- K010212 Offset Tibial Tray
- K033489 Biomet's Non-Cemented Porous Coated Knee Components

Device Description

The subject Biomet Tibial Trays are available in four design configurations – Interlok, porous, stemmed, and offset. The trays, as a system construct, are compatible with existing, legally marketed Biomet femoral components, tibial bearings, patella components, stems, screws, and various auxiliary components, including augment blocks and wedges.

This submission includes a modification to remove the shot peen operation from the manufacturing process of the subject Biomet Tibial Trays. In addition, a new cementing

technique option is being introduced for the Interlok tibial trays. The technique is executed via use of new implant-specific instrumentation referred to as CementON Tibial Molds.

Intended Use and Indications for Use
Biomet Tibial Trays are modular components that are part of a total knee implant system intended to replace the damaged or diseased knee joint during 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) devices and all-polyethylene patellar components are indicated for cemented application only.

Regenerex components are intended only for uncemented biologic fixation application.

Summary of Technological Characteristics
The subject changes include removal of the shot peen operation from the manufacturing process and the addition of a new cementing technique option for the Interlok trays via use of new implant-specific instrumentation.

The subject modifications do not result in any changes to the intended use, indications for use, materials, design features, or sterilization of the Biomet Tibial Trays.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
  - Tibial Tray Cyclic Fatigue Testing
  - I-beam Implant Pullout Force from a Cement Mantle after CementON or Manual Cement Application
  - Finned Implant Pullout Force from a Cement Mantle after CementON or Manual Cement Application
- Clinical Tests
  - Clinical data was not required to establish substantial equivalence between the subject Biomet Tibial Trays and the predicate device.

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.