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

December 18, 2014

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

Re: K143009
Trade/Device Name: Echo Bi-Metric Microplasty Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, KWZ, JDI, KWL, LWJ, KWY, OQG, OQH, OQI, PBI
Dated: October 16, 2014
Received: October 20, 2014

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 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

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)*

K143009

Device Name

Echo Bi-Metric Microplasty Hip System

Indications for Use *(Describe)*

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty

Porous coated components are intended for uncemented, biological fixation.

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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Premarket Notification [510(k)] Submission, 21 CFR § 807.87
Echo Bi-Metric Microplasty Hip System

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46581-0857
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Julie B. Gantenberg, M.S., RAC
Date prepared	December 5, 2014
Name of device	
Trade or proprietary name	Echo Bi-Metric Microplasty Hip System
Common or usual name	Hip Prosthesis
Classification name	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358) Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310) Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350) Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360) Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390)

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Classification panel	Orthopedic
Regulation	21CFR 888.3358 21 CFR 888.3353 21 CFR 888.3310 21 CFR 888.3350 21 CFR 888.3360 21 CFR 888.3390
Product Code(s)	LPH, LZO, KWZ, JDI, KWL, LWJ, KWY, OQG, OQH, OQI, PBI
Legally marketed device(s) to which equivalence is claimed	Predicate Devices: K070274 Echo Bi-Metric Press Fit Stem (Biomet) K110400 Taperloc® Complete Microplasty System (Biomet) K050251 Balance Hip System Microplasty Stem (Biomet) Reference Devices: K090757 Biomet Modular Femoral Revision System (Biomet) K133184 Ardis Interbody system (Zimmer) K130610 Sirius Femoral Stem (Biomet)
Reason for 510(k) submission	Submission of Echo Bi-Metric Microplasty Hip System
Device description	The Echo Bi-Metric Microplasty Hip System consists of the subject Echo Bi-Metric Microplasty Hip stem component and legally marketed Biomet modular heads and/or acetabular components for total hip or hemi hip arthroplasty. The subject hip stem combines the design features of the standard length Echo Bi-Metric Press-Fit Stems but offers a shortened stem length design within the legally marketed shortened stem lengths using the same previously cleared materials. Patient contacting, reusable implant specific instruments are manufactured from stainless steel and include an aluminum titanium nitride (AlTiN) PVD or titanium nitride (TiN) PVD coating.
Intended use of the device	The proposed device system is an orthopaedic joint intended to replace the damaged or diseased natural hip joint in total hip or hemi hip arthroplasty to provide pain relief and restore function. The hip system is modular in design, consisting of the subject monolithic, femoral stem along with previously cleared, legally marketed compatible Biomet modular heads and/or acetabular components for total hip or hemi hip arthroplasty.

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Indications for use	1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis. 2. Rheumatoid arthritis. 3. Correction of functional deformity. 4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. 5. Revision of previously failed total hip arthroplasty Porous coated components are intended for uncemented, biological fixation.

The technological characteristics of the Echo Bi-Metric Microplasty Hip System are the same as those of predicate devices (K070274, K110400 and K050251) in terms of design, material, and principle of operation with the exception of slight modifications as described in this 510(k). Differences include a shortened stem and rounded lateral shoulder when compared to the K070274 primary predicate.

The Echo Bi-Metric Microplasty Hip Stems are proximally fitting, porous coated shortened stems for uncemented, biological fixation. Stem lengths are within the range of legally marketed short stems also cleared for biological fixation. The subject femoral stem utilizes the identical manufacturing processes as the predicates. The subject stem substrate and plasma spray coating are identical to that of K070274 and K090757. The previously cleared, porous plasma spray characterization data on identical substrate was provided in K090757 and used in support of subject 510(k). The subject non-clinical testing was conducted to demonstrate that the differences did not adversely affect safety and efficacy, and to demonstrate substantial equivalence to the predicate components. All testing met or exceeded the established acceptance criteria. This information is detailed below in the Performance (Non-clinical) section. Additionally, Biocompatibility information was provided in support of the implant specific instrument material.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS

Performance Test Summary-New Device

The following tests/were performed for the new Echo Bi-Metric Microplasty Hip System:

- Range of Motion
- Femoral Stem Proximal Fatigue
- Femoral Stem Distal Fatigue
- Biocompatibility (Implant Specific Instrument material)

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

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Clinical Performance Data/Information: N/A

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
No clinical testing was necessary for a determination of substantial equivalence. The results of mechanical testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.