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

November 2, 2016

Biomet Manufacturing Corporation
Mr. Brian Kincaid
Global Project Manager, Regulatory Affairs - SET
56 East Bell Drive
Warsaw, Indiana 46582

Re: K140652
Trade/Device Name: Porous Coated Comprehensive® Fracture Stems
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWT, KWS, MBF, HSD
Dated: April 4, 2014
Received: April 8, 2014

Dear Mr. Kincaid:

This letter corrects our substantially equivalent letter of July 3, 2014.

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,

Lori A. Wiggins -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)*
K140652

Device Name
Porous Coated Comprehensive® Fracture Stems

Indications for Use *(Describe)*
The Porous Coated Comprehensive® Fracture Stems are indicated for:
1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2) Rheumatoid arthritis.
3) Revision where other devices or treatments have failed.
4) Correction offunctional deformity.
5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
6) Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Humeral/glenoid components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation.) Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation).

The Comprehensive® Fracture Stems are intended for use with the Bio-Modular Humeral Heads and glenoid components and Versa-Dial Humeral Heads.

The Comprehensive™ Humeral Positioning Sleeves are for cemented use only and are intended for use with the Comprehensive™ Fracture Stem.

The Comprehensive™ Shoulder Stems (Fracture, Primary and Revision) are intended for use with the Bio-ModularTM Humeral Heads and glenoid components and Versa-DialTM Humeral Heads.

The Versa-Dial™ Humeral Head Prosthesis is intended for use only with the ComprehensiveTM Shoulder Stems (Fracture, Primary and Revision), the Bio-Modular™ Shoulder Stems, the glenoid components of the Bio-ModularTM Shoulder System, and the glenoid components of the Comprehensive™ Shoulder System.
When a humeral stem and/or Versa-DialTM Taper Adapter is being used for a reverse shoulder application, the user should refer to the package insert (01-50-0903) continued with the reverse shoulder components for additional information, including alternate indications.

Type of Use *(Select one or both, as applicable)*

Prescription Use (Part 21 CFR 801 Subpart D) D Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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JUL 0 3 2014

Section 5 - 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 46582	
Phone number	(574) 267-6639	
Fax number	(574) 372-1718	
Establishment Registration Number	1825034	
Name of contact person	Brian Kincaid	
Date prepared	March 7, 2014	
Name of device		
Trade or proprietary name	Porous Coated Comprehensive® Fracture Stems	
Common or usual name	Shoulder Replacement Prosthesis	
Classification name	Regulation	Product Code
Shoulder joint metal/polymer non-constrained cemented prosthesis	21 CFR 888.3650	KWT
Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis	21 CRF 888.3660	KWS
Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous-coated uncemented prosthesis	21 CFR 888.3670	MBF
Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis	21 CFR 888.3690	HSD
Classification panel	Orthopedics	
Legally marketed device(s) to which equivalence is claimed	Comprehensive Humeral Fracture Stems (K023063) Comprehensive Primary Shoulder Stems (K060692) Kirschner® Neer-III™ Modular Proximal Humerus (K874643)	
Reason for 510(k) submission	Line extension	
Device description	Biomet's Porous Coated Comprehensive® Fracture Stems consist of a humeral stem comprised of cast Co-Cr-Mo. The Proximal body of the stem contains 4 fins, three of which include suture holes to facilitate multiple attachment sites for the bone. The proximal body also contains a porous plasma-spray coating, which will allow	

	for optimum fixation of the stem in the proximal humerus. The humeral stem contains a reverse taper which allows for the use of either a Bio-Modular® humeral head or glenoid component, a Versa-Dial® humeral head, or the Comprehensive® Reverse Shoulder humeral components.
Indications for use	The Porous Coated Comprehensive® Fracture Stems are indicated for : 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis. 2) Rheumatoid arthritis. 3) Revision where other devices or treatments have failed. 4) Correction of functional deformity. 5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate. 6) Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate. Humeral/glenoid components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation.) Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation). The Comprehensive® Fracture Stems are intended for use with the Bio-Modular Humeral Heads and glenoid components and Versa-Dial Humeral Heads. The Comprehensive™ Humeral Positioning Sleeves are for cemented use only and are intended for use with the Comprehensive™ Fracture Stem. The Comprehensive™ Shoulder Stems (Fracture, Primary and Revision) are intended for use with the Bio-Modular™ Humeral Heads and glenoid components and Versa-Dial™

	Humeral Heads. The Versa-Dial™ Humeral Head Prosthesis is intended for use only with the Comprehensive™ Shoulder Stems (Fracture, Primary and Revision), the Bio-Modular™ Shoulder Stems, the glenoid components of the Bio-Modular™ Shoulder System, and the glenoid components of the Comprehensive™ Shoulder System. When a humeral stem and/or Versa-Dial™ Taper Adapter is being used for a reverse shoulder application, the user should refer to the package insert (01-50-0903) continued with the reverse shoulder components for additional information, including alternate indications.
Summary of The Technological Characteristics Compared to the Predicate	
The new device is identical or similar in design, materials, and intended use as the predicate devices. Design differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness.	
PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS	
Median Fatigue Test	
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
No clinical data submitted	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
No clinical data was necessary for a determination of substantial equivalence. The results of testing indicated the devices did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.	