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

November 2, 2016

Biomet Manufacturing Corporation
Ms. Patricia S. Beres
Senior Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K131353
Trade/Device Name: Comprehensive® Reverse Shoulder – Titanium Glenosphere
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, PAO
Dated: August 27, 2013
Received: August 29, 2013

Dear Ms. Beres:

This letter corrects our substantially equivalent letter of October 8, 2013.

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

Indications for Use

510(k) Number (if known): K131353

Device Name: Comprehensive® Reverse Shoulder - Titanium Glenosphere

Indications For Use:

The Comprehensive® Reverse Shoulder is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Comprehensive® Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Titanium glenospheres are intended for patients with colbalt alloy material sensitivity. The wear of these devices has not been tested but, based on pin on disk testing, the wear rate is inferior to that of cobalt alloy glenospheres. A cobalt alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the Macro Bond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

BIOMET®
MANUFACTURING CORP.

OCT 08 2013

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) 372-1683	
Establishment Registration Number	1825034	
Name of contact person	Patricia S. Beres Senior Regulatory Specialist Biomet Manufacturing Corp.	
Date prepared	October 8, 2013	
NAME OF DEVICE		
Trade name	Comprehensive® Reverse Shoulder - Titanium Glenosphere	
Common name	Glenosphere prosthesis	
Classification name	**Regulation**	**Product Code**
Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis	21 CFR 888.3660	KWS
Shoulder joint metal/polymer (+additive) semi-constrained cemented prosthesis	21 CFR 888.3660	PAO
Classification panel	Orthopedics	
Legally marketed device(s) to which equivalence is claimed	Comprehensive® Reverse Shoulder (K080642, K120121) BioModular® Shoulder System (K030710, K093803)	
Reason for 510(k) submission	New device	
Device description	The Titanium Alloy Glenosphere Prosthesis consists of a series of various sized modular glenospheres with variable offset between 0.5mm and 4.5 mm. Titanium alloy material has been selected to provide the surgeon with an alternate material to treat patients with nickel allergies. Each modular glenosphere consists of a "head" and a taper adaptor. The taper adaptor is impacted into the head in a certain position to achieve the desired amount of offset. The system can be used with Biomet's Comprehensive® Reverse Shoulder System or Biomet's BioModular® Reverse Shoulder System.	

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www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Indications for use	Biomet® Comprehensive Reverse Shoulder products are indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary. The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. Titanium glenospheres are intended for patients with colbalt alloy material sensitivity. The wear of these devices has not been tested but, based on pin on disk testing, the wear rate is inferior to that of cobalt alloy glenospheres. A cobalt alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to cobalt alloy. Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation. Interlok finish humeral stems are intended for cemented use and the MacroBond coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications. The device is a single-use implant.
SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE	
	The number of components, sizing, and all dimensions are identical to the predicate.

PERFORMANCE DATA
Non-Clinical Tests Conducted For Determination Of Substantial Equivalence
Torsional separation of tapers
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 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.