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 Sandborn Beres
Senior Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46581-0857

Re: K113069
Trade/Device Name: Comprehensive® Reverse Shoulder Humeral Tray
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: October 13, 2011
Received: October 17, 2011

Dear Ms. Beres:

This letter corrects our substantially equivalent letter of January 11, 2012.

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): K113069

Device Name: Comprehensive® Reverse Shoulder Humeral Tray

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.

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.

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

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113069

K113069 JAN 11 2012

BIOMET MANUFACTURING CORP.

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	Patricia Sandborn Beres Senior Regulatory Specialist Biomet Manufacturing Corp.
Date prepared	October 13, 2011
NAME OF DEVICE	
Trade or proprietary name	Comprehensive® Reverse Shoulder Humeral Tray
Common or usual name	Shoulder Prosthesis
Classification name	Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis
Classification panel	Orthopedics
Regulation	21 CFR 888.3660
Product Code(s)	KWS
Legally marketed device(s) to which equivalence is claimed	Comprehensive® Reverse Shoulder 510(k) K080642
Reason for 510(k) submission	Product improvement
Device description	The Comprehensive® Reverse Shoulder is intended for total shoulder replacement in a reverse shoulder configuration. Unlike traditional total shoulder replacement, a reverse shoulder employs a ball for articulation on the glenoid side of the joint and a polyethylene bearing surface on the humeral side of the joint. This device configuration increases the lever arm of the deltoid muscle bundle to provide stability and the ability to raise the arm. This is especially useful in cases where a patient has a non-functioning rotator cuff which severely limits traditional joint replacement options.
Intended use of the device	Shoulder Replacement
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.

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Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

K113069

Indications for use (continued)	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.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE

Characteristic	Modified Device	Comprehensive® Reverse Shoulder 510(k) K080642
Humeral Tray	Sizes: 44mm (std, +5mm, +10mm) Finish: No change Material: Ti-6Al-4V and Co-Cr-Mo Attachment: No change Angle: No change	Sizes: 44 & 49mm (std, +5mm, +10mm) Finish: Smooth Material: Ti-6Al-4V Attachment: Taper Angle: 45°
Humeral Bearing	No Changes	UHMWPE (ArComXL®, 1020 E-Poly™) 31, 36, 41mm Std, Std +3mm, Retentive +3mm Ringloc® snap ring
Glenoid Baseplate	No Changes	Diameter: 28mm Surface Finish: PPS/HA Material: Ti-6Al-4V Fixation: Screws
Glenoid Screws	Styles: Fixed/Locking, Fixed Non-Locking Material: No change Diameter: No change Lengths: No change Drive Slot: 2.5 Hex	Styles: Fixed/Locking, Fixed Non-Locking, Variable Locking Material: Ti-6Al-4V Diameter: 4.75mm Lengths: 15-45mm Drive Slot: Hexalobular
Glenosphere	No Changes	Diameters: 31, 36, 41mm Offset: Std, +3mm, +6mm Material Co-Cr-Mo Attachment to Base: Taper

PERFORMANCE DATA

Summary Of Non-Clinical Tests Conducted For Determination Of Substantial Equivalence

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
Fatigue Strength	None	The median fatigue strength was greater for the modified devices compared to the predicate device.
Polyethylene Properties	ASTM F-648	All properties exceed the requirements of ASTM F-648

Summary of clinical tests conducted for determination of substantial equivalence and/or of clinical information

No clinical data submitted

K113069

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
No clinical data was necessary for a determination of substantial equivalence. The results of mechanical testing indicated the device 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.