



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Biomet Manufacturing Corporation  
Ms. Patricia Sandborn Beres  
Senior Regulatory Specialist  
56 East Bell Drive  
Warsaw, Indiana 46582

May 16, 2016

Re: K152754

Trade/Device Name: Comprehensive Vault Reconstruction System (VRS)  
Regulation Number: 21 CFR 888.3660  
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: Class II  
Product Code: PHX  
Dated: March 29, 2016  
Received: March 31, 2016

Dear Ms. Beres:

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 Parts 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

## Indications for Use

510(k) Number (if known)  
K152754

Device Name  
Comprehensive Vault Reconstruction System

### Indications for Use (Describe)

Biomet Comprehensive Vault Reconstruction System 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 Vault Reconstruction System is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

The Comprehensive Vault Reconstruction System glenoid baseplate components are intended for cementless application with the addition of screw fixation in patients with unusual anatomy and/or extensive bone loss which precludes the use of a standard glenoid baseplate component.

Titanium glenospheres are intended for patients with Cobalt 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.

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.

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.

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### 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 Comprehensive Vault Reconstruction System (VRS) 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.

SUBMITTER INFORMATION	
<b>Name</b>	Biomet Manufacturing Corp.
<b>Address</b>	56 East Bell Drive Warsaw, IN 46582
<b>Phone number</b>	(574) 267-6639
<b>Fax number</b>	(574) 371-1027
<b>Establishment Registration Number</b>	1825034
<b>Name of contact person</b>	Patricia Sandborn Beres Senior Regulatory Specialist Biomet Manufacturing Corp.
<b>Date prepared</b>	May 10, 2016
NAME OF DEVICE	
<b>Trade or proprietary name</b>	Comprehensive Vault Reconstruction System (VRS)
<b>Common or usual name</b>	Shoulder Prosthesis
<b>Classification name</b>	Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis
<b>Classification panel</b>	Orthopedics
<b>Regulation</b>	21 CFR 888.3660
<b>Product Code(s)</b>	PHX
<b>Legally marketed device(s) to which equivalence is claimed</b>	Comprehensive Reverse Shoulder 510(k) K120121
<b>Reason for 510(k) submission</b>	New Device
<b>Device description</b>	The Comprehensive Vault Reconstruction System (VRS) is a glenoid baseplate for reverse shoulder arthroplasty designed to match the anatomy of an individual patient.
<b>Intended use of the device</b>	Shoulder Replacement
<b>Indications for use</b>	Biomet Comprehensive Vault Reconstruction System 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 Vault Reconstruction System is indicated for

	<p>primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.</p> <p>The Comprehensive Vault Reconstruction System glenoid baseplate components are intended for cementless application with the addition of screw fixation in patients with unusual anatomy and/or extensive bone loss which precludes the use of a standard glenoid baseplate component.</p> <p>Titanium glenospheres are intended for patients with Cobalt 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.</p> <p>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.</p>
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**SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE GLENSPHERE BASEPLATE COMPARED TO THE PREDICATE**

The new device is identical or similar in design, materials and intended use as the predicate device. Design differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness.

	<b>Proposed Device</b>	<b>Predicate Device - K120121</b>
<b>Glenoid Baseplate Materials</b>	same	Titanium Alloy per ASTM F136 Titanium Alloy plasma spray coating per ASTM F1580 Hydroxyapatite coating per ASTM F1185
<b>Glenoid Baseplate Size Range</b>	Envelope of sizes M/L and A/P dimension ≥ 25mm varied thickness 4.5mm to 50mm	Round 25mm diameter single thickness of 4.5mm
<b>Manufacturing Process</b>	Same	Machined from wrought Titanium with Plasma Spray and HA coating
<b>Other Design Feature</b>	Patient matched tray back 3-10 peripheral screw holes to accept locking and non-locking screws Medial Boss with 6.5mm screw	Flat tray back 4 peripheral screw holes to accept both locking and non-locking screws Medial Boss with 6.5mm screw
<b>Glenosphere attachment</b>	same	Mini Taper, requires taper adapter
<b>Other</b>	Pre-assembled with F.A.S.T. Guide Inserts	

<b>PERFORMANCE DATA</b>
<b>Summary Of Non-Clinical Tests Conducted For Determination Of Substantial Equivalence</b>
<b>Performance Test Summary-New Device</b>
Compressed Shear Load to Failure Testing
Baseplate Fixation Testing
Axial Separation Testing
Torsional Separation Testing
Software Validation
Cadaver Validation
<b>Summary of clinical tests conducted for determination of substantial equivalence and/or of clinical information</b>
No clinical data submitted
<b>CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA</b>
No clinical data was necessary for a determination of substantial equivalence. The results of 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.