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 46582
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Patricia Sandborn Beres Senior Regulatory Specialist
Date prepared	December 5, 2011
DEVICE INFORMATION	
Name of device	
Trade or proprietary name	Comprehensive® Segmental Revision System (SRS)
Common or usual name	Shoulder, elbow and total humeral replacement prosthesis
Classification name	• Shoulder joint metal/polymer non-constrained cemented prosthesis • Shoulder joint metal/polymer semi-constrained cemented prosthesis • Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous coated uncemented prosthesis • Elbow joint metal/polymer constrained cemented prosthesis
Classification panel	Orthopedics
Regulation	21 CFR§888.3650/3660/3670/3150
Product Code(s)	KWT, KWS, MBF, JDC
Legally marketed device(s) to which equivalence is claimed	• K043505- Discovery® - Mosaic® Total Humeral System • K042321- Mosaic® Non-Modular Proximal Body and EAS Offset Modular Humeral Head • K033280 - Discovery® Elbow - Mosaic® Proximal Humeral Replacement System • K020045 - 3-Piece Proximal Humeral Replacement System • K022079 – Short and Long Tissue Attachment Sleeves • K925613 - Proximal Humeral Replacement System • K030710 – Bio-Modular® Shoulder System
Reason for 510(k) submission	Update of existing product line
Device description	The Comprehensive® SRS address the needs of the upper extremity, especially in cases where there is marked bone loss. Applications of the system include proximal humeral (shoulder) replacements distal humeral (elbow) replacements and total humeral replacements. Components of the system include humeral heads, proximal humeral bodies, intercalary segments, humeral stems, total humeral couplers, distal bodies with a modular flange, and modular tissue attachment augments.

Indications for use	The Comprehensive® Segmental Revision System is intended for use in cases of: 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. Oncology applications including bone loss due to tumor resection. When used in a proximal or total humeral replacement, the Comprehensive® Segmental Revision System is also intended for: Treatment of acute or chronic fractures with humeral head (shoulder) involvement, which are unmanageable using other treatment methods. When used as a distal or total humeral replacement, the Comprehensive® Segmental Revision System is also intended for: Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement, which are unmanageable using other treatment methods.
Intended use of the device	The Comprehensive® Segmental Revision System is intended for use with or without bone cement in the proximal shoulder. The Comprehensive® Segmental Revision System is intended for use with bone cement in distal humeral and total humeral applications. Tissue Attachment Augments provide the option for tissue stabilization and attachment.

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

Characteristic	Comprehensive® SRS	Predicate
Materials	Ti-6Al-4V Co-Cr-Mo	K020045 K020045
Principal of Operation	Proximal humeral, distal humeral or total humeral replacement	K925613, K020045, K033280, K043505
Proximal Bodies	Resection Levels – 42-71mm Taper Head Attachment	K020045 K030710
Humeral Stems	Diameters – 4-20mm Lengths – 75-200mm Porous Coating Proximally	K020045, K033280, K925613 K020045, K033280, K925613 K020045, K033280, K030710
Intercalary Segments and Couplers	Diameter – 19mm Lengths – 30-120mm	K020045, K033280, K043505 K020045, K033280, K043505
Tissue Attachment	Augments	K022079
Humeral Heads	Diameters – 40-54mm Extended Articular Surface	K030710 K042321, K030710
Distal Humeral Bodies	Resection Height – 50, 60, 70mm Modular Flange	K033280, K043505 K051975

K111746

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PERFORMANCE DATA
Summary Of Non-Clinical Tests Conducted For Determination Of Substantial Equivalence
Engineering analysis to determine weakest point of the construct
Engineering analysis to determine range of motion
Engineering analysis to justify smaller diameter long stems
Cantilever fatigue testing to compare stem strength to predicate
Cyclic loading followed by screw torque out to confirm augment stability
Engineering analysis for flange loading determination
Cyclic fatigue testing of humeral flange
Static Axial Separation of SRS taper junction
Static Axial Separation of Comprehensive® taper junction
Shear testing to determine elbow condyle strength
MR Compatibility to ASTM F2182-09
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 analysis and 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

DEC 15 2011

Re: K111746
Trade/Device Name: Comprehensive® Segmental Revision System (SRS)
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, KWS, MBF, JDC
Dated: December 12, 2011
Received: December 13, 2011

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

fs/ Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111746

Device Name: Comprehensive® Segmental Revision System (SRS)

Indications For Use:
The Comprehensive® Segmental Revision System is intended for use in cases of:

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. Oncology applications including bone loss due to tumor resection.

When used in a proximal or total humeral replacement, the Comprehensive® Segmental Revision System is also intended for:

Treatment of acute or chronic fractures with humeral head (shoulder) involvement, which are unmanageable using other treatment methods.

When used as a distal or total humeral replacement, the Comprehensive® Segmental Revision System is also intended for:

Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement, which are unmanageable using other treatment methods.

The Comprehensive® Segmental Revision System is intended for use with or without bone cement in the proximal shoulder.

The Comprehensive® Segmental Revision System is intended for use with bone cement in distal humeral and total humeral applications.

Tissue Attachment Augments provide the option for tissue stabilization and attachment.

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)

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

510(k) Number K111746