BIOMET MANUFACTURING CORP.

JAN 2 2 2014

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) 371-3024	
Fax number	(574) 371-1027	
Establishment Registration Number	1825034	
Name of contact person	Carmen Albany, DVM Senior Regulatory Specialist Biomet Manufacturing Corp.	
Date prepared	April 19, 2013	
NAME OF DEVICE		
Trade name	StageOne™ Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis	
Common name	Bone Cement shoulder spacer mold; Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis; StageOne™ Shoulder Spacer Mold	
Classification name	**Regulation**	**Product Code**
Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis	21 CFR 888.3690	HSD
Shoulder joint metal/polymer semi-constrained cemented prosthesis	21 CFR 888.3660	KWS
Polymethylmethacrylate (PMMA) bone cement	21 CFR 888.3027	MBB
Classification panel	Orthopedics	
Legally marketed device(s) to which equivalence is claimed	Comprehensive Total Shoulder Standard Stem (K060692) StageOne™ Disposable Cement Spacer Mold For Temporary Hip Prosthesis with Reinforcement Stem (K052990) Tecres InterSpace® Shoulder (K112983)	
Reason for 510(k) submission	New device	
Device description	The single-use cement spacer molds are sterile disposables made of medical grade silicone. They are designed to be filled with Cobalt™ HV with Gentamicin bone cement by injecting with a dispenser/gun into the mold. After the cement cures, the hemi-shoulder prosthesis is to be removed from the mold and placed into the joint space. The hemi-shoulder prosthesis remains in place (180 days or less) until the second stage of the two-stage procedure is performed to implant a conventional shoulder joint prosthesis.	

Indications for use		Disposable cement spacer molds are indicated for use to mold a temporary hemi-shoulder replacement for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary prosthesis is molded using Cobalt™ HV with Gentamicin Bone Cement and inserted into the humeral medullary canal and glenoidal cavity following removal of the existing total shoulder replacement implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection). The hemi-shoulder prosthesis made from the StageOne™ disposable cement molds is not intended for use more than 180 days, at which time it must be explanted and permanent devices implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.) Due to the inherent mechanical limitations of the hemi-shoulder prosthesis material (Cobalt™ HV with Gentamicin Bone Cement), the temporary hemi-shoulder prosthesis is only indicated for patients who will consistently follow activity limitations throughout the implant period.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATES

The StageOne™ Shoulder Spacer Molds materials, design and sizing configurations are the same when compared to the named predicates. The sizing configurations of the StageOne™ Shoulder Spacer Molds are based on the Comprehensive Total Shoulder Standard Stem (K060692). The StageOne™ Shoulder Spacer Molds utilize the same silicone as used in the StageOne™ Hip Spacer molds (K052990). The StageOne™ shoulder spacers are made of the same material (polymethylmethacrylate/gentamicin bone cement) as the InterSpace® shoulder spacer (K112983) with the exception that the InterSpace® spacer contains a reinforcement structure made of stainless steel and the StageOne™ shoulder spacers do not.

PERFORMANCE DATA

Non-Clinical Tests Conducted For Determination Of Substantial Equivalence

Comparative mechanical (fatigue and static strength) was performed on the temporary shoulder prosthesis made with the StageOne™ shoulder spacer molds and the predicate Tecres InterSpace® Shoulder (K112983). Antibiotic (gentamicin) elution testing was performed on both the temporary shoulder prosthesis made with the StageOne™ shoulder spacer molds and the predicate Tecres InterSpace® Shoulder (K112983). The temporary shoulder prostheses were found to be substantially equivalent in fatigue and static strength characteristics. The percentage of total gentamicin eluted from the spacer made from a StageOne™ shoulder spacer mold and Cobalt™ HV with Gentamicin bone cement was substantially equivalent to the percentage of gentamicin eluted from the predicate Tecres InterSpace® Shoulder (K112983).

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.

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

January 22, 2014

Biomet Manufacturing Corporation
Carmen Albany, DVM
Senior Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K131135
Trade/Device Name: StageOne™ Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: MBB, HSD, KWS
Dated: December 5, 2013
Received: December 9, 2013

Dear Dr. Albany:

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 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lori A. Wiggins

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): K131135

Device Name: StageOne™ Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis __

Indications For Use:

Disposable cement spacer molds are indicated for use to mold a temporary hemi-shoulder replacement for skeletally mature patients undergoing a two-stage revision procedure due to a septic process. The temporary prosthesis is molded using Cobalt™ HV with Gentamicin Bone Cement and inserted into the humeral medullary canal and glenoidal cavity following removal of the existing total shoulder replacement implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The hemi-shoulder prosthesis made from the StageOne™ disposable cement molds is not intended for use more than 180 days, at which time it must be explanted and permanent devices implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.)

Due to the inherent mechanical limitations of the hemi-shoulder prosthesis material (Cobalt™ HV with Gentamicin Bone Cement), the temporary hemi-shoulder prosthesis is only indicated for patients who will consistently follow activity limitations throughout the implant period.

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)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131135