AUG 0 6 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 46581-0857
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Tracy Bickel Johnson, RAC
Date prepared	July 25, 2013
Name of device	
Trade or proprietary name	Signature™ Personalized Patient Care System – Glenoid Guide System
Common or usual name	Shoulder instruments
Classification name / Regulation	• prosthesis, shoulder, semi-constrained, metal/polymer cemented (§ 888.3660) • prosthesis, shoulder, non-constrained, metal/polymer cemented (§ 888.3650) • prosthesis, shoulder, semi-constrained, metal/polymer + additive, cemented (§ 888.3660) • prosthesis, shoulder, semi-constrained, metal/polymer, uncemented (§ 888.3670)
Classification panel	Orthopedic
Product Code(s)	KWS, KWT, PAO, and MBF
Legally marketed device(s) to which equivalence is claimed	• (Reference Device) Modular Hybrid Access Glenoid/Comprehensive Reverse Shoulder Instruments (Biomet, Inc.)- 510(k) Exempt • NaviPro Shoulder System (Kinamed, Inc.)- K050897 • Signature Personalized Patient Care System- Acetabular Guide System (Materialise, NV)- K111863
Reason for 510(k) submission	New patient specific glenoid guides
Device description	Patient specific guides are designed and manufactured in plastic using additive manufacturing. The guides are developed using patient imaging scans, software, and the clinician approved/finalized pre-surgical plan. The guides facilitate the placement of metallic pins and can be used in conjunction with existing anatomic and reverse Biomet instrumentation and surgical techniques.
Intended use of the device	Intraoperative placement of metallic bone pins in arthroplasty procedures.
Indications for use	The **Signature Personalized Patient Care System – Glenoid Guide System** is intended to be used as a surgical instrument to assist in the positioning of glenoid components intra-operatively using anatomical landmarks of the shoulder that are identifiable on

	preoperative imaging scans. The **Signature Personalized Patient Care System – Glenoid Guide System** can be used in conjunction with the Comprehensive Total and Reverse Shoulder Systems (including the Modular Hybrid Glenoid, Bio-Modular Heads and Stems), and their respective components, which require placement of an initial center pin or hole to guide the associated system instruments. The **Signature Glenoid Guide** is intended for single use only.

Summary of the Technologies

Signature™ Glenoid Guide System consists of various software systems to create patient specific glenoid guides to facilitate the orientation of the central pin for glenoid preparation. The CT patient imaging data is collected preoperatively and used to create three-dimensional "models" which are then transferred to a glenoid template resulting in a guide that can place anatomic and reverse shoulder components.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS

Performance Test Summary-New Device

- Accuracy performance testing (cadaver lab) and Guide verification of post processing techniques and autoclave sterility deformation dimensional stability testing was performed to determine substantial equivalence.
- Planned trajectories analysis for Signature and Predicate
- Packaging/Sterilization Testing
- Pathologic Model Analysis

Testing verified that the accuracy and performance of the system is adequate to perform as intended.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information: N/A

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

No clinical testing was necessary for a determination of substantial equivalence.

The results of 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 Center - WO66-G609
Silver Spring, MD 20993-0002

August 6, 2013

Biomet, Incorporated
% Ms. Tracy Bickel Johnson
Global Regulatory Project Manager
56 East Bell Drive
Warsaw, Indiana 46581

Re: K130126
Trade/Device Name: Signature™ Personalized Patient Care System – Glenoid Guide System
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBF, KWT, KWS, PAO
Dated: June 21, 2013
Received: June 24, 2013

Dear Ms. Johnson:

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" (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,

Erin I. Keith

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): K130126

Device Name: Signature™ Personalized Patient Care System – Glenoid Guide System

Indications For Use:

INDICATIONS FOR USE

The **Signature Personalized Patient Care System – Glenoid Guide System** is intended to be used as a surgical instrument to assist in the positioning of glenoid components intra-operatively using anatomical landmarks of the shoulder that are identifiable on preoperative imaging scans.

The **Signature Personalized Patient Care System – Glenoid Guide System** can be used in conjunction with the Comprehensive Total and Reverse Shoulder Systems (including the Modular Hybrid Glenoid, Bio-Modular Heads and Stems), and their respective components, which require placement of an initial center pin or hole to guide the associated system instruments.

The **Signature Glenoid Guide** is intended for single use only.

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