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

September 10, 2014

Biomet Manufacturing Corporation
Mr. Brian Kincaid
Global Project Manager - Regulatory SET
56 East Bell Drive
Warsaw, Indiana 46582

Re: K140390
Trade/Device Name: Titanium Versa-Dial™ Humeral Head Prosthesis
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, HSD, KWS, KWT
Dated: July 25, 2014
Received: July 31, 2014

Dear Mr. Kincaid:

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): K140390

Device Name: Titanium Versa-Dial™ Humeral Head Prosthesis
Indications for Use:

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. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
6. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Humeral components with a MacroBond surface coating are indicated for either cemented or uncemented press-fit applications.

Humeral/glenoid components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation).

Polyethylene glenoid components not attached to a metal back are indicated for cemented application only.

The Versa-Dial Humeral Head Prosthesis is intended for use only with the Comprehensive Shoulder Stems (Fracture, Primary and Revision), the Bio-Modular Shoulder Stems, the glenoid components of the Bio-Modular Shoulder System, and the glenoid components of the Comprehensive Shoulder System.

The Titanium Versa-Dial Humeral Head Prosthesis are indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium humeral head is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(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)

510(k) Summary

Preparation Date: September 5, 2014

Applicant/Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
FDA Registration Number 1825034

Contact Person: Brian Kincaid
Global Project Manager
Phone: (574) 372-3992
Fax: (574) 372-1718
Email: brian.kincaid@biomet.com

Proprietary Name: Titanium Versa-Dial™ Humeral Head Prosthesis

Common Name: Shoulder Prosthesis

Classification Code(s)/Name(s):
MBF – Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Uncemented (888.3670)
HSD – Prosthesis, Shoulder, Hemi-, Humeral, Metallic, Uncemented (888.3690)
KWS – Prosthesis, Shoulder, Semi-constrained Cemented Prosthesis (888.3660)
KWT – Non-Constrained, Metal/Polymer Cemented (888.3650)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

The predicate devices are the Versa-Dial® Humeral Head Prosthesis, K060716 and the Bio-Modular Humeral Heads with IonGuard, K915596 and K030710.

Device Description:

The Titanium Versa-Dial™ Humeral Head Prosthesis consists of a series of various-sized modular humeral heads with variable offset between 0.5mm and 4.5mm. The humeral heads consist of a shell head and a taper adaptor. The taper adaptor is impacted into the head in a certain position to achieve the desired amount of offset. The system can be used with Biomet's Comprehensive® Shoulder System or Biomet's BioModular® Shoulder System.

Intended Use:

The Titanium Versa-Dial™ Humeral Head Prosthesis is intended for:

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. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
6. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Humeral components with a MacroBond surface coating are indicated for either cemented or uncemented press-fit applications.

Humeral/glenoid components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation).

Polyethylene glenoid components not attached to a metal back are indicated for cemented application only.

The Versa-Dial Humeral Head Prosthesis is intended for use only with the Comprehensive Shoulder Stems (Fracture, Primary and Revision), the Bio-Modular Shoulder Stems, the glenoid components of the Bio-Modular Shoulder System, and the glenoid components of the Comprehensive Shoulder System.

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Summary of Technologies:

The Titanium Versa-Dial™ Humeral Head Prosthesis uses the same technology as the previously cleared Versa-Dial™ Humeral Head Prosthesis, K060716. The subject device is manufactured from Ti-6Al-4V, instead of Co-Cr-Mo which is used in the predicate Versa-Dial Heads cleared in K060716.

Non-Clinical Testing:

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Torsional separation testing was conducted to determine that the modified device did not introduce any new issues of safety or effectiveness. The testing showed that the titanium on titanium taper geometry met the acceptance criteria.

An engineering summary of previous testing related to axial disassembly of the Comprehensive Shoulder taper connection feature was provided to justify that the titanium on titanium mating material condition in the large portion of the taper (humeral head to taper adaptor) did not introduce new issues of safety and efficacy. The summary concluded that there were no new issues of safety and efficacy.

A comparative engineering analysis of design factors that influence in vivo wear behavior was conducted in order to demonstrate that the modified device did not introduce any new issues of safety or effectiveness. The results of the analysis indicate that that the wear of the subject device would be expected to be no worse than the K915596 and K030710 predicate device.

Clinical Testing:

No clinical data submitted.

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