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BIOMET
ORTHOPEDICS, INC.

510(k) Summary

DEC 1 1 2006

Preparation Date: December 8, 2006

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0588

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Phone: (574) 267-6639
FAX: (574) 372-1683

Proprietary Name: Modular Hybrid Glenoid

Common Name: Total shoulder replacement components

Classification Name:
1. Prosthesis, Shoulder, Non-constrained, Metal/Polymer, Cemented (21 CFR Section 888.3650)
2. Prosthesis, Shoulder, Semi-constrained, Metal/Polymer, Cemented (21 CFR Section 888.3660)

Legally Marketed Device to which Substantial Equivalence is claimed:

• Bio-Modular® Shoulder System (Biomet)	K030710, K992119
• The Trabecular Metal™ Glenoid (Zimmer)	K043061, K031449, K022377
• DePuy Global™ Shoulder Glenoid (DePuy)	K052472, K981487

Device Description: The Modular Hybrid Glenoid consists of a base and optional pegs. The polyethylene base has a concave articulating surface. The back side of the base has three outer polyethylene pegs for cement fixation and a central threaded titanium insert for the attachment of a central peg. The device may be used with or without a central peg.

The polyethylene peg has circumferential flanges. A titanium rod is molded within the peg to provide a threaded connection with the base.

The porous titanium peg provides the surgeon with an option for potential tissue ingrowth fixation. The peg is circular in design and tiered. Similar to the polyethylene peg, the porous titanium peg has a central titanium rod to provide a threaded connection.

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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

The Modular Hybrid Glenoid is intended to be inserted with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

Summary of Technologies: The materials, surface finishes and processing of the Modular Hybrid Glenoid are similar to the predicate device.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected clinical conditions. A full characterization of the porous titanium construct has been provided.

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp.
% Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

DEC 1 1 2006

Re: K060694
Trade/Device Name: Modular Hybrid Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer, semi-constrained, cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, KWT
Dated: November 20, 2006
Received: November 21, 2006

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060694

Indications for Use

510(k) Number (if known):_____

Device Name: Modular Hybrid Gleniod

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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 General, Restorative,
and Neurological Devices

510(k) Number K060694