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DEC 6 2005

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Allison Koskey

Proprietary Name: Porous Titanium Acetabular Augments

Common Name: Acetabular augments

Classification Name: Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous Uncemented (888.3358); Prosthesis, Hip, Semi-constrained, Metal/Polymer, Cemented (888.3350); Hip joint metal/polymer constrained cemented or uncemented prosthesis (888.3310); Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (888.3320); Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (888.3330); Hip joint metal/ceramic/polymer semi-constrained cemented or non porous uncemented prosthesis (888.3353)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Hedrocel® Acetabular Augment (K001471)

Device Description: The acetabular augments are constructed of porous titanium alloy conforming to ASTM F 1580-95. The augments range in outer diameter size from 48 mm to 58 mm in 2 mm increments. Each outer diameter will have three subsizes; small, medium, and large. The Porous Titanium Acetabular Augments incorporate screw holes that allow for the use of 6.5 mm bone screws, for adjunct fixation of the acetabular component and the native bone.

Intended Use: The Porous Titanium Acetabular Augments are indicated for cemented or non-cemented use in cases of:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

The porous titanium augments are intended to provide the orthopedic surgeon with a prosthetic alternative to structural allograft in cases of segmental deficiencies.

The porous titanium acetabular augment is affixed to the mating acetabular cup using bone cement. The assembled porous titanium augment/acetabular construct is intended for cemented or uncemented use.

The porous titanium acetabular augments are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery.

Summary of Technologies: The technological characteristics (material modification, design, sizing, indications) of the Porous Titanium Acetabular Augments are similar to or identical to the predicate device.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 6 2005

Allison Koskey
Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K052888
Trade/Device Name: Porous Titanium Acetabular Augments
Regulation Number: 21 CFR 888.3320
Regulation Name: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses
Regulatory Class: III
Product Codes: KWA, JDI, JDL, KWZ, LPH, LZO, MAY, MEH
Dated: October 10, 2005
Received: October 13, 2005

Dear Ms. Koskey:

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 (301) 594-4639. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/suppoty/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K052888

Device Name: Porous Titanium Acetabular Augments

Indications For Use:

The Porous Titanium Acetabular Augments are indicated for cemented or non-cemented use in cases of:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
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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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052888