K070369

BIOMET

510(k) Summary

MAR 0 9 2007

Preparation Date: March 7, 2007

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Robert Friddle, Regulatory Affairs Specialist

Proprietary Name: Regenerex™ RingLoc® + Modular Acetabular Shell

Common Name: Acetabular component for a total hip replacement

Classification Code(s)/Name(s): Class II

Product Classification Codes, Names and Regulation numbers:

1. JDG, prosthesis, hip, femoral component, cemented, metal 21 CFR 888.3360
2. JDI, prosthesis, hip, semi-constrained, metal/polymer, cemented 21 CFR 888.3350
3. KWZ, prosthesis, hip, constrained, cemented or uncemented, metal/polymer 21 CFR 888.3310
4. LPH, prosthesis, hip, semi-constrained, metal/polymer, porous Uncemented 21 CFR 888.3358
5. LWJ, prosthesis, hip, semi-constrained, metal/polymer, Uncemented 21 CFR 888.3360
6. LZO, prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, Uncemented 21 CFR 888.3353
7. MAY, prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish 21 CFR 888.3353
8. MBL, prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous 21 CFR 888.3358
9. MEH, prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate 21 CFR 888.3353

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Porous Coated Acetabular Components, 510(k) K050124, cleared October 4, 2005

Device Description: All devices are metallic, hemispherical, modular acetabular shell components. All shells have Regenerex™ (porous Ti-6Al-4V) applied to the exterior fixation surface. Each shell utilizes a modular polyethylene liner and a modular femoral head component that is a taper fit onto a femoral stem intra-operatively.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

K070369

Intended Use: Cemented or non-cemented total hip replacement in cases of:

1. Non-inflammatory 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 by other techniques.
5. Revision procedures where other treatment or devices have failed.

The indications for use of the constrained liners compatible with this system are as follow:
The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

Summary of Technologies: The devices covered by this 510(k) are geometrically similar or identical to the predicate.

Non-Clinical Testing: Device specific risk analysis resulted in performance of design verification bench tests and validation activities. The results of design verification and validation activities do not raise new issues of safety and effectiveness.

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 9 2007

Biomet Manufacturing Corp.
c/o Mr. Robert Friddle
Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K070369
Trade/Device Name: Regenerex™ RingLoc® + Modular Acetabular Shell
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, JDG, KWZ, LWJ, LZO, MAY, MBL, MEH
Dated: January 29, 2007
Received: February 8, 2007

Dear Mr. Friddle:

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.

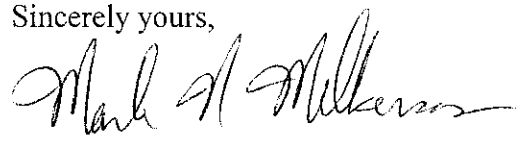
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

Enclosure

K070369

Indications for Use

510(k) Number (if known):_____

Device Name: Regenerex™ RingLoc® + Modular Acetabular Shell

Indications For Use: Cemented or non-cemented total hip replacement in cases of:

1. Non-inflammatory 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 by other techniques.
5. Revision procedures where other treatment or devices have failed.

The Indications for use of the constrained liners compatible with this system are as follow:
The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

Prescription Use YES (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)

Mark N Milhous

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

510(k) Number K070369