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APR 21 2008

BIOMET®
MANUFACTURING CORP.

510(k) Summary

Preparation Date: April 10, 2008

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Susan Alexander

Proprietary Name: Regenerex™ Tibial Components

Common Name: Tibial components

Classification Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (21 CFR §888.3565)

Product Code: MBH, JWH

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Regenerex™ Ultra Porous Construct-Femoral and Tibial Knee Augments	K053505	Biomet Manufacturing Corp.
Biomet's Non-Cemented Porous Knee Components	K033489	Biomet Manufacturing Corp.
Trabecular Metal Tibial and Patellar Components for the NexGen® Knee System	K031462	Zimmer/Implex Corporation
AGC® Revision Knee Prosthesis	K033489 K912245	Biomet, Inc.
Kirschner Performance Total Knee System Porous Coated	K874547	Kirschner Medical Corporation

Device Description: The Regenerex™ Tibial Components are intended for primary knee arthroplasty and utilize the existing Biomet tibial tray profile and sizing system.

Intended Use: Cemented or Uncemented

Indications for Use:

The indications for the Regenerex™ Tibial Components include:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

These devices are single-use implants intended for cemented or uncemented applications.

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

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Biomet Manufacturing Corp.
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Summary of Technologies: The technological characteristics (material, design and sizing) of the Regenerex™ Tibial Components are similar or identical to the predicate devices.

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

APR 21 2008

Biomet Manufacturing Com
% Ms. Susan Alexander
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581

Re: K080361
Trade/Device Name: Regenerex™ Tibial Components
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prothesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: February 8, 2008
Received: February 11, 2008

Dear Ms. Alexander:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

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Indications for Use

510(k) Number (if known):_____

Device Name: Regenerex™ Tibial Components

Indications For Use:

The indications for the Regenerex™ Tibial Components include:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

These devices are single-use implants intended for cemented or uncemented applications.

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)

Neil R P Ogden for mxm

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

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