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510(k) Summary

Sponsor: Biomet Manufacturing, Corp.
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy Bickel Johnson, RAC
Regulatory Associate
Biomet Manufacturing Corp.
(574) 267-6639

Proprietary Name: Titanium Femoral Knee Components (Maxim® and AGC®)

Common Name: Knee Femoral Components (K981996)

Classification Name: Cemented semi-constrained polymer/metal/polymer knee prosthesis (888.3560)

Substantially Equivalent Devices: Titanium Femoral Components (K981996)

Device Description: The femoral components found in this submission (AGC® and Maxim®) are identical to their predecessors (K981996) with the exception of the vendor who will complete the nitrogen ion implantation on the Ti-6Al-4V femoral surfaces.

Intended Use:

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

- Device designed for use in patients with metal sensitivity.
- Standard surgical and rehabilitative procedures are indicated with this device.
- The device is a single use device intended for use with bone cement.

Summary of Technologies: The femoral components in this submission have not been modified from their original state in terms of materials, design, sizing, and indications. The only modification is a vendor change for nitrogen ion implantation.

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

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

Tracy J. Bickel
Biomet Manufacturing Corporation
56 East Bell Drive
Warsaw, Indiana 46582

Re: K041466
Trade/Device Name: Titanium Femoral Knee Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: June 1, 2004
Received: June 2, 2004

Dear Ms.Bickel:

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) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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: Titanium Femoral Knee Components

Indications For Use:

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

- Device designed for use in patients with metal sensitivity.
- Standard surgical and rehabilitative procedures are indicated with this device.
- The device is a single use device intended for use with bone cement.

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)

Miriam C. Provost

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

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