MAR 10 1999

K98 1996

# SUMMARY OF SAFETY AND EFFECTIVENESS

**Sponsor:** Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

**Device:** Titanium Femoral Component

**Classification Name:** Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis (CFR 888.3560)

**Intended Use:** When used with the AGC and Maxim Knee Systems, the indications for use of the Titanium Femoral Component include 1)painful and disabled knee joint resulting from osteoarthritis, rheumatiod arthritis, or traumatic arthritis where one or more compartments are involved, 2)failure of a previous joint replacement procedure, 3)correction of varus, valgus or post traumatic deformity, and 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.

This device is a single use implant for use with bone cement

**Device Description:** The femoral components of the AGC and Maxim Knee Systems are identical to their Co-Cr-Mo predecessors with the exception of the material used in manufacturing and a limited component availability. The AGC titanium component is available in primary universal components of five different sizes. The Maxim titanium component is available in five sizes of the primary universal component and five sizes of the revision universal component.

The titanium components are all $N^+$ ion implanted, to Biomet engineering specification 1.4, in order to reduce the wear of both the titanium femoral component and the ultrahigh molecular weight polyethylene (UHMWPE).

**Potential Risks:** The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

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|---|---|---|
| Reaction to the bone cement | Blood vessel damage | Bone fracture |
| Deformity of the joint | Soft tissue imbalance | Infection |
| Cardiovascular disorders | Delayed wound healing | Hematoma |
| Fracture of the cement | Metal sensitivity | Dislocation |
| Implant loosening/migrating | Fracture of the component | Excessive wear |
| Nerve damage | | |

**Substantial Equivalence:** In function and overall design, the Titanium Femoral Component is equivalent to other knee components on the market. These components include:

Maxim Knee System (Biomet, Inc., Warsaw, IN)
AGC 2000 Total Knee Prosthesis (Biomet, Inc., Warsaw, IN)
MG II Total Knee (Zimmer, Inc., Warsaw, IN)
Kinemax Plus Total Knee System (Howmedia, Inc., Rutherford, NJ)
Genesis Total Knee System (Smith & Nephew Richards, Inc., Memphis, TN)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 1999

Mr. Fred McClure
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K981996
Titanium Femoral Components
Regulatory Class: II
Product Code: JWH
Dated: December 9, 1998
Received: December 10, 1998

Dear Mr. McClure:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.

2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

/s/

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K981996

DEVICE NAME: Titanium Femoral Component

INDICATIONS FOR USE:

When used with the AGC and Maxim Knee Systems, the indications for use of the Titanium Femoral Component include 1)painful and disabled knee joint resulting from osteoarthritis, rheumatiod arthritis, or traumatic arthritis where one or more compartments are involved, 2)failure of a previous joint replacement procedure, 3)correction of varus, valgus or post traumatic deformity, and 4)correction or revision of unsuccessful osteotomy or arthrodesis.

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Standard surgical and rehabilitative procedures are indicated with this device.

This device is a single use implant for use with bone cement.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981996

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

or

Over-The-Counter Use_____

(Optional Format 1-2-96)