K033489

JUN - 2 2004

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet, Inc.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Names: AGC® Total Knee System Knee, Ascent™ Total Knee System, Maxim® Complete Knee System, Maxim® Accel Knee System also known as the Vanguard Knee System

Common Name: Porous coated knee replacement components

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

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: AGC® Total Knee System Knee (K833921, K912245), Ascent™ Total Knee System (K982869, K994326), Maxim® Complete Knee System (K915132), Maxim® Accel Knee System (Vanguard) (K023546), Trabecular Metal Tibial and Patellar Components for the NexGen Knee System (K031462), Genesis II Total Knee System (K030612), Profix Total Knee System (K030623)

Device Description: All devices are metallic knee femoral and tibial base-plate components. The components are identical to those cleared in previous 510(k) submissions for cemented application.

The porous coated components that are subject of this 510(k) are intended for use with components (tibial bearings, all polyethylene patellar components, non-porous coated femoral and tibial base-plates) previously covered by 510(k) submission for cemented use.

Intended Use: Non-cemented total knee replacement

Indications for Use: The indications for Biomet's Non-Cemented Porous Coated Knee 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 of revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Summary of Technologies: The devices to be covered by this 510(k) are identical to devices covered by previously cleared 510(k) submissions for cemented application.

Clinical and Non-Clinical Testing: None provided

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2004

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedics, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K033489
Trade/Device Name: Biomet's Non-Cemented Porous Coated Knee Components
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Regulatory Class: II
Product Code: MBH
Dated: March 3, 2004
Received: March 4, 2004

Dear Ms. Beres:

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,

for Miriam C. Provost

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

Indications for Use

510(k) Number (if known): K033489

Device Name: Biomet's Non-Cemented Porous Coated Knee Components

Indications For Use: The indications for Biomet's Non-Cemented Porous Coated Knee 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 of revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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

510(k) Number K033489