APR 2 7 2000

K001018

SUMMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc.
Airport Industrial Park
P. O. Box 587
Warsaw IN 46580 –0587

CONTACT PERSON: Tina Lakin
(219) 267-6639 ext. 1816

DEVICE NAME: Ascent Knee Revision Femoral Stem

CLASSIFACTION NAME: Knee joint patello-femorotibial polymer/metal/polymer semi-constrained cemented prosthesis (CFR 888.3560).

INDICATIONS FOR USE: Ascent Knee Revision Femoral Stem is indicated for use in:

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) Corrections or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is for Cemented Use Only

DEVICE DESCRIPTION: The Ascent Knee Revision Stems are similar to the previously cleared Performance Posterior Stabilized (PS) Total Knee System (K936274) used to ensure component placement and stability. The modifications made add a larger and smaller diameter size, decrease the slot width, and change the stem material. The distal diameter on stems sized 10 – 16 were also increased. Minor modifications were also made to the femoral locking screw.

There are sixteen new wrought titanium alloy (Ti-6Al-4v) Ascent Revision Stems available. Twelve of these sixteen have the same diameter and length as the previously cleared Performance PS Total Knee System (K936274). The larger diameter revision stem has been added to fit within larger canals. The smaller diameter revision stem has been added to fit within smaller canals.

POTENTIAL RISKS: The potential risks with this device are the same with any other joint replacement device. These include, but are not limited to:

Reaction to bone cement	Fracture of bone cement	Hematoma
Fracture of component	Metal sensitivity	Nerve damage
Cardiovascular disorders	Implant loosening/migration	Infection
Blood vessel damage	Soft tissue loosening	Bone fracture
Deformity of the joint	Tissue growth failure	
Delayed wound healing	Dislocation	

SUBSTANTIAL EQUIVALENCE: The Ascent Knee Revision femoral stem is modified from the Performance P/S Knee femoral stem (Biomet – K936274).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2000

Ms. Tina Lakin
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

Re: K001010
Trade Name: Ascent Knee Revision Femoral Stems
Regulatory Class: II
Product Code: JWH
Dated: March 28, 2000
Received: March 29, 2000

Dear Ms. Lakin:

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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (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. 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 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R Lachman

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

510(k) NUMBER (IF KNOWN): K001010

DEVICE NAME: Ascent Knee Revision Femoral Stems

INDICATIONS FOR USE:

The Ascent Knee Revision Femoral Stem is indicated for:

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) Corrections or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is a single use implant

This device is for cemented use only

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Donna R. Bachner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001010