JUL 30

K984054

BIOMET INC®

CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Sponsor: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0578

Device: AGC V2 Revision Knee System

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (CFR 888.3560)

Indications:

1. Osteoarthritis, rheumatoid arthritis or traumatic arthritis
2. Failure of a previously failed joint replacement procedure
3. Correction of varus, valgus or post-traumatic deformity
4. Correction or revision of unsuccessful osteotomy or arthrodesis

The device is intended for use with bone cement (USA)

Device Description: The AGC V2 Revision Knee System is an extension of Biomet's knee families. Specifically, the devices are similar to the AGC Primary Knee cleared through 510(k) K833921, the AGC Revision (posterior stabilized) Knee cleared through 510(k) K912245 and Maxim Knee System cleared through K915132. The device consists of a femoral component with modular stems that articulates with a one-piece tibial component. The AGC V2 system employs Biomet's standard all polyethylene patella button.

Unique features of the AGC V2 System included the femoral stem angle being built into the stem itself rather than the boss of the femoral component like other systems. The device expands Biomet's existing AGC product line by providing a device with more constraint than current components and additional augments for the femoral component.

The AGC V2 tibial component provides a one-piece molded component with a high post posterior stabilized option. Pegs on the bottom of the tray provide stability for the augmentations.

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:

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/migration	Fracture of the components	Excessive wear
Nerve damage	Disassociation of components	

Substantial Equivalence: In function and overall design, Biomet's AGC V2 Revision Knee System is equivalent to almost all knee components on the market. These systems include:

AGC 2000 Total Knee Prosthesis (Biomet, Inc., Warsaw, IN)
AGC Revision Knee Prosthesis (Biomet, Inc., Warsaw, IN)
MCK (Maxim) Knee System (Biomet, Inc., Warsaw, IN)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet INC
Airport Industry Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K984054
Trade Name: AGC V2 Revision Knee System
Regulatory Class: II
Product Code: JWH
Dated: May 6, 1999
Received: May 7, 1999

Dear Ms. Sandborn Beres:

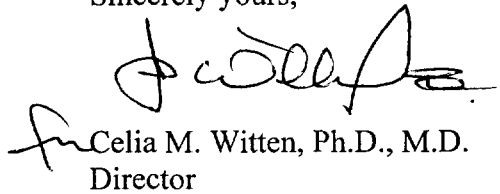
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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): K984054

Device Name: AGC V2 Revision Knee System

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984054

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)