K971938

BIOMET INC®

CORPORATE HEADQUARTERS

AUG 25 1997

Summary of Safety and Effectiveness

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

Device: Repicci II Unicondylar Knee

Classification Name: Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/Polymer (21 CFR 888.3530)

Intended Use: Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. The device is a single use implant intended for implantation with bone cement.

Device Description: The Repicci II Unicondylar Knee consists of femoral and tibial components. The femoral component is anatomic in design to provide coverage of the condyle from posterior to anterior. The anatomic shape of the femoral component necessitates separate left and right configurations. A central keel and post on the back of the device assist in cement fixation. The device is manufactured from cobalt alloy.

Two styles of tibial components are available with this system, an all polyethylene component and a modular metal backed component. The all polyethylene component is universal in geometry. A waffle pattern on the under surface assists in initial fixation. A modular tibial component consists of a metal tray and a polyethylene bearing which is snap fit into the tray by the surgeon.

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		

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE 219.267.6639 ■ FAX 219.267.8137 ■ E-MAIL biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sandborn Beres
Director, Regulatroy Affairs
BioMet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

AUG 25 1997

Re: K971938
Repicci II Unicondylar Knee
Regulatory Class: II
Product Code: HRY
Dated: May 23, 1997
Received: May 27, 1997

Dear Ms. 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). 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. The thinnest tibial insert available is the nominal "8.0mm" sized insert, which has a minimum polyethylene thickness under the condyles of 6.0mm.

2. The thinnest all-poly tibial tray component available is the nominal "8.5mm" sized component, which has a minimum polyethylene thickness under the condyles of 8.5mm.

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

4. 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.

5. 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,

for 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): K971938

Device Name: Repicci II Unicondylar Knee

Indications For Use:

Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

The device is a single use implant intended for implantation with bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971938