JUN 0 5 2002

K021621

BIOMET
CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Dalene T. Binkley
Telephone: (574) 267-6639

Proprietary Name: Fixed Bearing Uni Component

Common Name: Molded Uni Tibial Bearing

Classification: Prosthesis, knee, femorotibial, semi-constrained, cemented, metal/polymer (21 CFR 888.3530)

Device Classification: Class II

Legally Marketed Device to which Substantially Equivalence is Claimed: Repicci II™ Unicondylar Knee (K971938)

Device Description: The tibial component consists of polyethylene plateau molded over a one-piece Co-Cr-Mo base and central keel. The molded tibial components are anatomical in geometry with right and left medical/lateral allocations. The overall form of the implant is tear-shaped.

The Fixed Bearing Uni Components will be used in conjunction with the Oxford Unicompartmental Knee Femoral Component (K011138) and the Repicci II™ Unicondylar Knee (K971938).

Indications for Use: The indications for the Fixed Bearing Uni Components are for painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved; the correction of varus, valgus, or posttraumatic deformity; and the correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure. The Fixed Bearing Uni Components are for use with bone cement.

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

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

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219.267.8137

E-MAIL
biomet@biomet.com

Summary of Technologies: The Fixed Bearing Uni Components -the materials, design, sizing, and indications are similar or identical to the predicate devices.

Non-Clinical Testing: Engineering Justifications, Mechanical Testing, and a Finite Element Analysis (FEA) determined that the Fixed Bearing Uni Components presented no new risks and was, therefore, substantially equivalent to the predicate device.

Clinical Testing: No clinical testing was provided as a basis for substantial equivalence.

K021621

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 5 2002

Ms. Dalene T. Binkley
Regulatory Affairs Specialist.
Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K021621
Trade Name: Fixed Bearing Uni Component
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: April 26 2002
Received: May 16, 2002

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Mark N. Melkerson

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): K021621

DEVICE NAME: Fixed Bearing Uni Component

INDICATIONS FOR USE:

The Fixed Bearing Uni Component is indicated for use 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; and 3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is intended to be used 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 OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021621

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