JUL 1 0 2001

K011138

BIOMET INC

CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

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

Contact Person: Patricia Sandborn Beres
(219) 267-6639

Proprietary Name: Oxford™ Unicompartmental Knee Femoral Component

Common Name: Unicompartmental Knee Femoral Component

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

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Repicci™ II Unicondylar Knee (K971938) and AGC® Unicompartmental Femoral Component (K873601)

Device Description: The Oxford™ Unicompartmental Knee Femoral Component has a highly polished spherical articular surface. The inner surface of the prosthesis is, for the most part, spherically concave and concentric with the articular surface. Posteriorly there is a small, flattened surface, the plane of which lies parallel to the long axis of the femur. There is a central peg. This peg lies parallel to the mechanical axis of the femur. The component is available in four distinct sizes to allow for fit to patient anatomy.

Two styles of Repicci™ tibial components may be used with the Oxford™ Unicompartmental Knee Femoral Component, an all polyethylene component and a modular metal backed component.

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, deformity or revision of previous arthroplasty. The device is a single use implant intended for implantation with bone cement.

Summary of Technologies: The Oxford™ Femoral component technological characteristics (materials, design, sizing, and indications) are similar to or identical to the predicate devices.

Non-Clinical and Clinical Testing: None provided as a basis for substantial equivalence. Engineering analysis conducted to show strength of peg.

All trademarks are property of Biomet, Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 0 2001

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

Re: K011138
Trade Name: Oxford Unicompartmental Knee Femoral Component
Regulatory Class: II
Regulation Number: 888.3530
Product Code: HRY
Dated: April 12, 2001
Received: April 13, 2001

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). 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,

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): K011138

Device Name: Oxford™ Unicompartmental Knee Femoral Component

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, deformity or revision of previous arthroplasty. The device is a single use, cemented implant

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 011138

Prescription Use ___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)