JUL 2 6 2000

K001350

BIOMET INC®

CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0578

Proprietary Name: Patient Matched Trochlea

Classification Name: Knee joint patellofemoral, polymer/metal semi-constrained cemented prosthesis (21 CFR 888.3540)

Intended Use: Replacement of the patella and resurfacing of the femoral trochlear groove. The device is a single use implant intended to be implanted with bone cement.

Indications for Use:

1. Patients with osteoarthritis limited to the distal femur and patella
2. Patients with a history of patellar dislocation or patellar fracture
3. Those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

Device Description: Biomet's Patient Matched Trochlea Component is a patellofemoral device designed to match the natural geometry of an individual patient. Devices are designed in keeping within predefined basic geometric parameters unless otherwise requested by the surgeon. Devices typically employ a 1" radius patella groove compatible with Biomet's standard patella components. The patella groove of the device could be matched to a patient's natural patella geometry or a patella marketed by another manufacturer.

The devices are normally manufactured from Titanium alloy (Ti-6Al-4V) conforming to ASTM F-136. In such cases, the devices are ion implanted to improve the material wear properties. The rear surface of the device is most commonly grit blasted but may be have plasma spray porous coating.

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

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 component	
Excessive wear	Nerve damage	

Substantial Equivalence: Biomet's Patient Matched Trochlea components are substantially equivalent to other devices on the market. These include Sulzer Othopeadics' (formally Intermedics Orthopedics) Patellofemoral Joint Prosthesis and Smith-Nephew Richards' Patello-Femoral Replacement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 6 2000

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

Re: K001350
Trade Name: Patient Matched Titanium Alloy Trochlea Replacement
Regulatory Class: II
Product Code: KRR
Dated: April 27, 2000
Received: April 28, 2000

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,

Donna R. Lochner

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): K001350

Device Name: Patient Matched Titanium Alloy Trochlea Replacement

Indications For Use:

1. Patients with osteoarthritis limited to the distal femur and patella
2. Patients with a history of patellar dislocation or patellar fracture
3. Those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

The device is a single use implant intended to be implanted with bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001350

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)