JUN 2 3 2000

K000827

Summary of Safety and Effectiveness
for
Unicompartmental PatelloFemoral Prosthesis System

This safety and effectiveness summary for the Unicompartmental PatelloFemoral Prosthesis System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
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Contact Person :
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Date Prepared: March , 10 2000

2. Tradename: Unicompartmental PatelloFemoral Prosthesis (UPP) System
Common Name: Patellofemoral Joint Prosthesis
Classification Name: Knee Joint, Patellofemoral, Polymer / Metal, Semi-constrained, Cemented Prosthesis (888.3540)

3. Predicate or legally marketed devices which are substantially equivalent:

- Patella I, II, III System (S &N Richards)
- The Worrell Patella Prosthesis and Femoral Shield (DePuy)
- The Patello Femoral Knee Prosthesis (Wright Medical)
- Patellofemoral Joint Prosthesis (Sulzer / Intermedics)
- The Bechtol Patello-Femoral Joint Replacement (Richards Mfg Co.)

4. Description of the device :

The Unicompartmental PatelloFemoral Prosthesis is a joint replacement system designed to replace the diseased portions of the patellofemoral articulation. It consists of femoral and patellar implant components, and the instrumentation to implant them.

Materials: The implants are manufactured from cast CoCrMo alloy and ultra high molecular weight polyethylene (UHMWPE) per ASTM standards.

Function: The system functions to provide relief of pain due to arthritis of the patellofemoral joint, or a history of dislocation or patellar fracture.

5. Intended Use:

The Unicompartmental PatelloFemoral Prosthesis is generally indicated for use in patients with osteoarthritis in the patellofemoral joint, or a history of patellar dislocation or patellar fracture, and in patients with failed previous surgery where pain. deformity or dysfunction persists.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the Unicompartmental PatelloFemoral Prosthesis System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2000

Walter Abendschein, M.D.
5530 Wisconsin Avenue, Suite 705
Chevy Chase, Maryland 20815

Re: K000827/S001
Trade Name: Unicompartmental Patellofemoral Prosthesis (UPP) System
Regulatory Class: II
Product Code: KRR
Dated: June 7, 2000
Received: June 8, 2000

Dear Dr. Abendschein:

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

for 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) : K000827

Device Name : **Unicompartmental Patellofemoral Prosthesis System**

Indications For Use :

The Unicompartmental Patellofemoral Prosthesis System is indicated for use in patients with osteoarthritis in the patellofemoral joint, or a history of patellar dislocation or patellar fracture, and in patients with failed previous surgeries where pain, deformity or dysfunction persists.

For Cemented Use Only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dianne R Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000827

Prescription use X
(PER 21 CFR 801.109)

OR

Over-the-counter use _____

(optional format 1-2-96)