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AUG 14 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(K) CONTACT: Sally Foust
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TRADE NAME: DePuy Proximal Femoral Replacement Prosthesis

COMMON NAME: Hip Prosthesis

CLASSIFICATION: 888.3358 Hip joint metal/polymer semi-constrained porous coated uncemented prosthesis

DEVICE PRODUCT CODE: 87LPH

SUBSTANTIALLY EQUIVALENT DEVICES:

- Porocoat Proximal Femoral Third Prosthesis
- Proximal Femur Replacement Stem
- Solution Hip Prosthesis
- 5/8 Porocoat AML Hip Prosthesis

DEVICE DESCRIPTION AND INTENDED USE: The DePuy Proximal Femoral Replacement Prosthesis is indicated for uncemented and cemented use as the femoral component in total hip arthroplasty for replacing the hip joint in the following indications, as appropriate: 1) a severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis, 2) avascular necrosis of the femoral head, 3) acute traumatic fracture of the femoral head or neck, 4) failed previous surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement, and 5) certain cases of ankylosis. It is a porous coated (except for the tapered distal tip), straight, cast Co-Cr-Mo stem available in three femoral sizes. The stem has a driving platform, a self-locking 12/14, 0540" taper for attachment of interchangeable modular femoral heads.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The Proximal Femoral Replacement Prosthesis is similar to the Porocoat Proximal Femoral Third Prosthesis, Proximal Femur Replacement Stem, Solution Hip Prosthesis and 5/8 Porocoat AML Hip Prosthesis which have been previously cleared by FDA. The intended use of the Proximal Femoral Replacement Prosthesis is for uncemented and cemented applications just like the Solution Hip Prosthesis, whereas the Porocoat Proximal Femoral Third Prosthesis and Proximal Femur Replacement Stem is intended for cemented use only. The stem and porous coating material, Co-Cr-Mo alloy, for the Proximal Femoral Replacement Prosthesis is identical to that of the Porocoat Proximal Femoral Third Prosthesis and the Solution Hip Prosthesis, whereas the stem and porous coating material for the

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Proximal Femur Replacement Stem is Ti-6Al-4V. All of the above stems are porous coated. The placement of the porous coating on the total stem, except for the distal tapered tip, for the Proximal Femoral Replacement Prosthesis is identical to that of the Solution Hip Prosthesis, whereas the porous coating for the Porocoat Proximal Femoral Third Prosthesis and the Proximal Femur Replacement Stem is on the distal stem and the entire stem respectively. The Proximal Femoral Replacement Prosthesis, Porocoat Proximal Femoral Third Prosthesis, and the Solution Hip Prosthesis each has a "bullet" tapered distal tip, whereas the Proximal Femur Replacement Stem has a "rounded" non-tapered distal tip. The Proximal Femoral Replacement Prosthesis and the Proximal Femur Replacement Stem are collarless, whereas the Porocoat Proximal Femoral Third Prosthesis has a mid stem "step" and the Solution Hip Prosthesis has a collar. The Proximal Femoral Replacement Prosthesis, the Proximal Femur Replacement Stem and the Solution Hip Prosthesis are designed to accept modular femoral heads, whereas the Porocoat Proximal Femoral Third Prosthesis is a non-modular design with the femoral head attached.

The subject Proximal Femoral Replacement Prosthesis is similar to the Proximal Femur Replacement Stem previously cleared by FDA with the exception of the change in taper/neck design, the tapered distal stem without porous coating, the material change to Co-Cr-Mo, and the addition of an uncemented use indication. The manufacturing process, intended use (with the exception of the additional indication of uncemented use) and the basic design of the Proximal Femoral Replacement Prosthesis with a 12/14 taper have not changed from those of the Proximal Femur Replacement Stem cleared by FDA in 1990.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sally Foust
Clinical Affairs Associate
DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

AUG 14 1997

Re: K970241
Trade Name: DePuy Proximal Femoral Replacement
(PFR) Prosthesis
Regulatory Class: II
Product Codes: LPH, JDI, and LZO
Dated: June 19, 1997
Received: June 20, 1997

Dear Ms. Foust:

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 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.

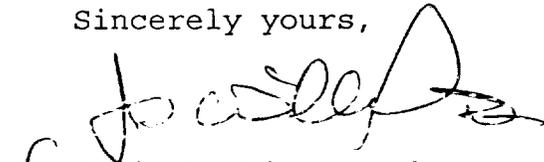
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


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) K970241

Device Name DePuy Proximal Femoral Replacement Prosthesis

Indications for Use:

The DePuy Proximal Femoral Replacement Prosthesis is indicated for uncemented or cemented use as the femoral component in total hip arthroplasty for replacing the hip joint in the following indications, as appropriate: 1) a severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis, 2) avascular necrosis of the femoral head, 3) acute traumatic fracture of the femoral head or neck, 4) failed previous surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement, and 5) certain cases of ankylosis.

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970241

Prescription Use X OR Over-The Counter Use ____ (Per 21 CFR 801.109)