JUN 19 1997

K964650

SAFE MEDICAL DEVICES ACT OF 1990
510K SAFETY AND EFFECTIVENESS SUMMARY

NAME OF FIRM:	DePuy Inc. P.O. Box 988 Warsaw, IN 46581-0988
510(k) CONTACT:	Vickie E. Arford, R.N. Sr. Clinical Research Associate
TRADE NAME:	TCP-coated Porocoat® AML® Femoral Hip Prosthesis
CLASSIFICATION NAME:	Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous Uncemented, Calcium-Phosphate
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Inc. AML® ⅝ Porocoat® Femoral Implant (P820024, K941847)

INTENDED USE AND DEVICE DESCRIPTION:
The primary objective of total hip arthroplasty in general is to provide for increased mobility in the patient by reducing pain and replacing the damaged hip joint articulation.

This femoral hip prosthesis, with an appropriate Co-Cr-Mo alloy (Orthochrome®) metal femoral ball, is intended to be used as the femoral component in total hip replacement. This femoral hip prosthesis is indicated for cementless use and fixation by biological tissue ingrowth into the porous coating.

This prosthesis may be used where x-ray evidence of sufficient sound bone to seat the femoral component exists. The prosthesis may be used for total hip replacement 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.
5. Certain cases of ankylosis.

The TCP-coated Porocoat® AML® Femoral Hip Prosthesis is a ⅝ porous coated, straight-stemmed, collared prosthesis with a thin coating of tricalcium phosphate sprayed onto approximately ½ of the porous coating of the implant and is designed to be used as the femoral component in total hip replacement without cement.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The TCP-coated Porocoat® AML® Femoral Hip Prosthesis and the DePuy Inc. AML® ⅝ Porocoat® Femoral Implant are both intended for cementless use as the femoral component in total hip replacement. The devices are identical except for the thin coating of TCP plasma sprayed onto approximately ½ of the proximal porous coating.Clinical results show that the TCP-coated Porocoat® AML® Femoral Hip Prosthesis is comparable to the DePuy Inc. AML® ⅝ Porocoat® Femoral Implant.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 1997

Vickie E. Arford, R.N.
Senior Clinical Research Associate
DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K964650
TCP-coated Porocoat® AML® Femoral Hip Prosthesis
Regulatory Class: II
Product Codes: LPH and MEH
Dated: March 20, 1997
Received: March 21, 1997

Dear Ms. Arford:

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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

> You may not label or in any way promote these devices for enhanced clinical or radiographic performance, enhanced biological fixation and/or long-term stable fixation. The data presented support equivalence with no additional claims over a conventional porous-coated uncemented hip prosthesis (i.e., biological fixation, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.

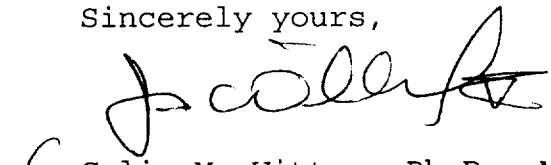
You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,



for 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: K964650

Device Name: TCP-coated Porocoat® AML® Femoral Hip Prosthesis

Indications for Use:

The TCP-coated Porocoat® AML® Femoral Hip Prosthesis, with an appropriate Co-Cr-Mo alloy metal femoral ball, is intended to be used as the femoral component in total hip replacement. This femoral hip prosthesis is indicated for cementless use and fixation by biological tissue ingrowth into the porous coating.

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5. Certain cases of ankylosis.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K964650

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)