

K984459

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR OF THIS 510(K): DePuy Orthopaedics, Inc.
a *Johnson & Johnson* company
P.O. Box 988
700 Orthopaedics Drive
Warsaw, Indiana 46581-0988

510(K) CONTACT: Sally Foust
Sr. Regulatory Associate
DePuy Orthopaedics, Inc.
a *Johnson & Johnson* company
(219) 372-7455; FAX (219) 267-7098

TRADE NAME: DePuy Profile® Femoral Hip with Porocoat®

COMMON NAME: Hip Device

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

DEVICE CODE: 87LPH

EQUIVALENT DEVICES: DePuy Stability Hip System with Porocoat®
(K934457) (Uncemented, K934457)
DePuy Profile® Femoral Hip Prosthesis with Porocoat®
(Cemented, K872776)
DePuy Hydroxyapatite Coated Profile® Hip Stem
(Press-Fit, K910156)
DePuy Profile® Femoral Hip (Press-Fit, K850055)

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Profile® Hip with Porocoat® prosthesis is identical in design and materials to the DePuy Profile® Hip with Porocoat® prosthesis cleared by FDA for cemented use (K872776). The prosthesis is designed with an anatomical conformance to the medullary canal, proximal porous-coating, rounded distal taper, and 12/14 femoral neck taper which allows for the use of interchangeable modular femoral heads. The prosthesis is available in six sizes, each are available in right and left configurations.

The DePuy Profile® Femoral Hip with Porocoat® prosthesis is indicated for uncemented or cemented use as the femoral component in total hip arthroplasty (THA) for replacing the hip joint of a patient whose hip joint has been damaged by inflammatory or non-inflammatory degenerative joint disease, fracture or the failure of a previous arthroplasty.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Profile® Hip with Porocoat® prosthesis is similar in design (proximal porous coating, anatomical, and modular heads), identical in material (Ti-6Al-4V alloy) and intended use (uncemented) to the previously cleared DePuy Stability Hip (K934457).

With the exception of the additional intended use (uncemented), the DePuy Profile® Femoral Hip with Porocoat® prosthesis is identical in design, material (Ti-6Al-4V alloy) and intended use (cemented) to the previously cleared DePuy Profile® Femoral Hip with Porocoat® prosthesis (K872776). The material (Ti-6Al-4V alloy conforming to ASTM F-620), manufacturing process and design of the DePuy Profile® Hip with Porocoat® prosthesis, including stem diameters, location of the porous coating and characteristics of the porous coating will not be changed from those of the DePuy Profile® Hip with Porocoat® prosthesis previously cleared (K872776) by FDA.

The DePuy Profile® Hip with Porocoat® prosthesis is identical in material (Ti-6Al-4V alloy), similar in design (proximal porous coating, anatomical, and modular heads), and similar in intended use (uncemented) to the previously cleared DePuy Profile® Hip with Hydroxyapatite (K910156) and DePuy Profile® Hip (K850055).

Based on the information provided in this premarket notification, DePuy considers the DePuy Profile® Hip with Porocoat® prosthesis to be substantially equivalent to uncemented hip prostheses that are currently legally marketed.

The following table summarizes the similarities:

	Profile® Porocoat® (this submission)	Stability K934457	Profile® Porocoat® K872776	Profile® Hydroxyapatite K910156	Profile® K850055
Intended Use	Uncemented	Uncemented	Cemented	Press-Fit	Press-Fit
Stem Material	Ti-6Al-4V ASTM-620	Ti-6Al-4V ASTM-620	Ti-6Al-4V ASTM-620	Ti-6Al-4V ASTM-620	Ti-6Al-4V ASTM-620
Proximal Surface Coating	Porocoat® Porous-coating	Porocoat® Porous-coating	Porocoat® Porous-coating	Hydroxyapatite	None
Design	Anatomical	Anatomical	Anatomical	Anatomical	Anatomical
Modular Heads	Yes	Yes	Yes	Yes	Yes
Modular Taper	12/14mm	12/14mm	12/14mm	12/14mm	12/14mm

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 28 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K984459
Trade Name: DePuy Profile® Femoral Hip with Porocoat®
Regulatory Class: II
Product Code: LPH
Dated: December 14, 1998
Received: December 15, 1998

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.

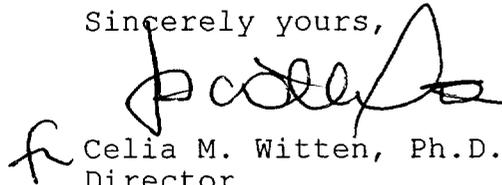
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) K984459

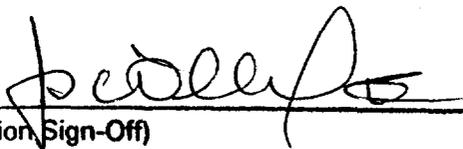
Device Name: DePuy Profile Femoral Hip with Porocoat: Additional Indication

Indications for Use:

The DePuy Profile Femoral Hip with Porocoat prosthesis is indicated for uncemented or cemented use as the femoral component in total hip arthroplasty (THA) for replacing the hip joint of a patient whose hip joint has been damaged by inflammatory or non-inflammatory degenerative joint disease, fracture or the failure of a previous arthroplasty.

Concurrence of CDRH, Office of Device Evaluation

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



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984459

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