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510(k) Summary

NAME OF SPONSOR:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(K) CONTACT:	**Karla A. Ham** Senior Regulatory Associate Phone: (574) 371-4925 FAX: (574) 371-4987
TRADE NAME:	**Pinnacle Duofix™ HA Acetabular Cup Prosthesis**
COMMON NAME:	Acetabular Cup Prosthesis
CLASSIFICATION:	**Class II** Device per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
DEVICE PRODUCT CODE:	**87LPH**
SUBSTANTIALLY EQUIVALENT DEVICES:	**Acetabular Cup:** DePuy Pinnacle Acetabular System, K000306 **HA Porous Coating**: DePuy TriFlange Acetabular Cup K001277

DEVICE DESCRIPTION:

The Pinnacle Duofix HA Acetabular Cup Prosthesis is a sintered, porous-coated (Porocoat®) hemispherical outer acetabular shell manufactured from titanium alloy (Ti-6Al-4V) with a thin layer of hydroxyapatite (HA) coating applied.

The interior of the acetabular cup is designed with a groove and a taper for use with either an ultra-high molecular weight polyethylene (UHMWPE) or metal acetabular cup liner, which lock into the shell. Articulation occurs between the liner, and a femoral head with the appropriately sized diameter.

The shells contain an apical threaded hole to allow the surgeon to attach the shell insertion instrument and grasp the shell during implantation. An optional titanium alloy (Ti-6Al-4V) apical hole plug is available to screw into the threaded apical hole of the shell. The plug is intended to occlude the apical hole in order to prevent particulate migration and provide polyethylene support.

The Pinnacle Duofix HA Acetabular Cup Prosthesis is provided in shell diameter sizes 48mm through 66mm in both the "No Hole" (100 series) and the "Cluster Hole" (Sector series) configurations.

510(k) Summary (cont.)

INTENDED USE AND INDICATIONS:
The Pinnacle Duofix HA Acetabular Cup Prosthesis is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Duofix HA Acetabular Cup Prosthesis is indicated for cementless application.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Based on similarities of design, materials, sterilization processes, and the same intended use, DePuy believes that the Pinnacle Duofix HA Acetabular Cup is substantially equivalent to the previously cleared Pinnacle Acetabular System, K000306.

In addition, DePuy believes that the hydroxyapatite (HA) coating applied to the Pinnacle Duofix HA Acetabular Cup Prosthesis is substantially equivalent to the HA coating applied to the DePuy TriFlange Acetabular Cup, cleared in K001277.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2003

Ms. Karla A. Ham
Senior Regulatory Associate
Depuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K031495
Trade/Device Name: Depuy Pinnacle Duofix™ HA Acetabular Cup Prosthesis
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained, porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: April 25, 2003
Received: May 14, 2003

Dear Ms. Ham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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): K031495

Device Name: Pinnacle Duofix™ HA Acetabular Cup Prosthesis

Indications for Use:

The Pinnacle Duofix™ HA Acetabular Cup Prosthesis is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Duofix HA Acetabular Cup Prosthesis is indicated for cementless application.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter Use No

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031495