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510(k) Summary

DEC 1 0 2002

NAME OF FIRM:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) CONTACT:	Karla Ham Sr. Regulatory Affairs Associate
TRADE NAME:	DePuy Pinnacle Metal-on-Metal Acetabular Cup Liner
COMMON NAME:	Acetabular Cup Prosthesis
CLASSIFICATION:	888.3330: Hip joint metal/metal semi-constrained, with uncemented acetabular component, prosthesis; **Class III**
DEVICE PRODUCT CODE:	87 ~~JDM~~ KWA
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Pinnacle Metal-on-Metal Acetabular Cup Liner, K002883

DEVICE DESCRIPTION:
The Pinnacle Metal-On-Metal Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner is offered in both 28 mm and 36 mm inner diameter (ID) sizes with outer diameters (OD) ranging from 48mm through 66mm. The liner is offered in neutral style only. The metal-on-metal liner is mechanically locked with the acetabular shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

INTENDED USE AND INDICATIONS:
The Pinnacle Metal-On-Metal Acetabular Cup Liner is indicated for use as the acetabular component 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 non-union of femoral fractures. Use of this prosthesis is also indicated 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 28mm Metal-On-Metal Acetabular Cup Liners are intended for use with the DePuy Pinnacle Acetabular Shells and 28 mm diameter Co-Cr-Mo femoral heads.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The Pinnacle Metal-On-Metal Acetabular Cup Liners in 44mm OD x 28mm ID and 46mm OD x 28mm ID sizes are identical to the previously cleared Pinnacle Metal-On-Metal Acetabular Cup Liners, K002883. The additional outer diameter sizes of 44mm and 46mm are manufactured from the same material and have the same intended use as the previously cleared device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2002

Ms. Karla A. Ham
DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581

Re: K023786
Trade/Device Name: DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners
Regulation Number: 21 CFR 888. 3330
Regulation Name: Hip Joint Metal/metal Semi-constrained with Uncemented Acetabular Component, Prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: November 8, 2002
Received: November 13, 2002

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) 594-4659. 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" (21CFR Part 807.97). 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,

for Mark N Melkerson

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): K023786

Device Name: **DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners**

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation

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

for Mark N Milhous

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

510(k) Number K023786

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