OCT 1 3 2000

K002883

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) CONTACT:	Cheryl Hastings Director, Regulatory Affairs
TRADE NAME:	DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners
COMMON NAME:	Acetabular Cup Prosthesis
CLASSIFICATION:	888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
DEVICE PRODUCT CODE:	87 JDM
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Ultima Metal-On-Metal Acetabular Cup

DEVICE DESCRIPTION AND INTENDED USE:
The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner has a 28mm inner diameter and is offered in a neutral style only. The Pinnacle MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

It 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 the 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 Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 28mm diameter Co-Cr-Mo femoral heads only.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The Pinnacle Metal-On-Metal Acetabular Cup Liners are nearly identical to the Ultima Metal-On-Metal Acetabular Cup Liners that were cleared previously. The intended use, articular surface, material and locking mechanism with the outer shell are the same. The only changes are minor design changes that allow the liners to be used with the Pinnacle Acetabular Shells that have been cleared previously.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2000

Ms. Cheryl K. Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K002883
Trade Name: Pinnacle Metal-On-Metal Acetabular Cup Liners
Regulatory Class: III
Product Codes: JDM and KWA
Dated: September 13, 2000
Received: September 15, 2000

Dear Ms. Hastings:

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 control provisions of the Act. The general control 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.

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 at (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, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K002883

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

Indications for Use:
The Pinnacle Metal-On-Metal Acetabular Cup Liners are 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 the 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.

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NKo for CMW

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002883

Concurrence of CDRH, Office of Device Evaluation

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