MAY 2 8 2004

K040544

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF SPONSOR: DePuy® Inc.
P.O. Box 988
Warsaw, IN 46581-0988
Registration Number: 1818910

510(k) CONTACT: Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
Telephone: (574) 371-4905
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TRADE NAME: Duraloc® Option Acetabular Cup System
COMMON NAME: Hip Prosthesis

REGULATORY CLASSIFICATION: 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; 888.3353 Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented, CLASS II

DEVICE PRODUCT CODE: 87 LPH and 87 LZO

SUBSTANTIALLY EQUIVALENT DEVICES:

- DePuy Pinnacle Acetabular System (K001534)
- DePuy Duraloc Cementless Acetabular Cup System (K961186)

DEVICE DESCRIPTION AND INTENDED USE:

The Duraloc® Option Acetabular Cup System consists of a UHMWPE acetabular cup liner secured to a porous-coated Ti-6Al-4V acetabular shell. The acetabular system articulates with previously cleared 28mm femoral heads, as well as with 22.225mm femoral heads internally documented by DePuy as line extensions to femoral heads cleared in K920317 and K980513.

The 28mm femoral heads were cleared in K920317 on March 19, 1992, K893872 on July 11, 1989, K883460 on October 11, 1998, K860701 on March 19, 1986, K891082 on June 9, 1989 and K011533 on January 28, 2002.

The acetabular cups are sized from 46mm to 66mm, in 2 mm increments. The liners are available in two styles: neutral and lipped. Liners with a 22.225mm inner diameter are offered in the outer diameter of 46mm. Liners with a 28mm inner diameter are offered in outer diameters of 48/50mm, 52mm, 54/56mm, 58/60mm, and 62/64/66mm.

The liner interlock allows the liner to be rotated to match the patient's anatomy. A locking ring, manufactured from Co-Cr-W-Ni alloy, is used to secure the liner.

The cups and liners are intended to be used in total hip arthroplasty to provide increased patient mobility and to reduce pain by replacing damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

The acetabular cups are indicated for cementless application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2004

Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
DePuy, Inc.
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K040544
Trade/Device Name: Duraloc® Option Acetabular Cup System
Regulation Number: 21 CFR 888.3358 and 888.3353
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis and Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LPH and LZO
Dated: March 1, 2004
Received: March 2, 2004

Dear Dr. Weissman:

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.

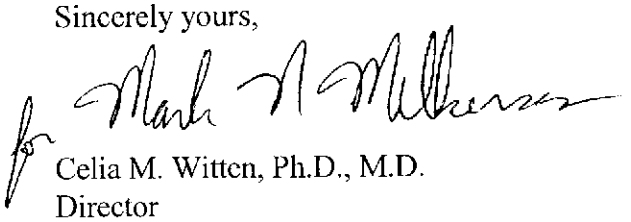
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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. 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 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,



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

Indications for Use

510(k) Number (if known): **K040544**
Device Name: **Duraloc® Option Acetabular Cup System**
Indications for Use:

The Duraloc® Option Acetabular Cup System is for total hip replacement.

A total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The acetabular cups are indicated for cementless application.

Prescription Use XXXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K040544