

K972596

NOV 12 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(k) CONTACT: Cheryl Hastings
Manager, Clinical Affairs

TRADE NAME: DePuy Duraloc® Acetabular Cup System

COMMON NAME: Acetabular Cup Prosthesis

CLASSIFICATION: 888.3358 Hip joint metal/polymer semi-constrained
cementless prosthesis

DEVICE PRODUCT CODE: 87 LPH

**SUBSTANTIALLY EQUIVALENT
DEVICES:** Modified DePuy Acetabular Cup System

DePuy Modified AML+ Acetabular Cup System

DEVICE DESCRIPTION AND INTENDED USE:

The subject DePuy Duraloc Acetabular Cup Liners are polyethylene acetabular cup liners which are available with 28mm or 32mm inner diameters, and with a neutral or a 10° lip. The 28mm liners are available in sizes to fit Duraloc metal acetabular shells with outer diameters of 48-74mm. The 32mm liners are available in sizes to fit Duraloc metal acetabular shells with outer diameters of 52-74mm. The Duraloc polyethylene liners are locked into the Duraloc metal shells with a metal wire locking ring which is supplied with the metal shells. The subject polyethylene liners are identical in design to the acetabular cup liners cleared with the Modified DePuy Acetabular Cup System and the DePuy Modified AML+ Acetabular Cup System.

The only difference between the subject Duraloc polyethylene liners and those that have been previously cleared by FDA is that the subject liners are manufactured from cross-linked polyethylene which has physical and mechanical properties that are similar to those of standard UHMWPE but has increased resistance to oxidation compared to gamma radiation sterilized standard UHMWPE.

The DePuy Duraloc Acetabular Cup Liners are intended to be used with the DePuy Duraloc metal acetabular shells to resurface the acetabular socket in cemented or cementless total hip replacement

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cheryl Hastings
Manager, Clinical Affairs
DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

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Re: K972596
Trade Name: DePuy Duraloc® Acetabular Cup System
Regulatory Class: II
Product Codes: LPH and JDI
Dated: October 22, 1997
Received: October 23, 1997

Dear Ms. Hastings:

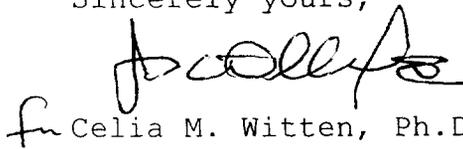
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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.

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,


for 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) K972596

Device Name DePuy Duraloc Acetabular Cup Liners

Indications for Use:

The DePuy Duraloc Acetabular Cup Liners are intended to be used with the Duraloc System Acetabular Cups to resurface the acetabular socket in cemented or cementless total hip arthroplasty.

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972596

Prescription Use

OR
(Per 21 CFR 801.109)

Over-The Counter Use _____

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