

DEC 2 1998

K98349/

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF SPONSOR: DePuy®, Inc.
P.O. Box 988
Warsaw, Indiana 46581-0988

510(k) CONTACT: Sally Foust
Senior Regulatory Submissions Associate
DePuy Orthopaedics, Inc.
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E-Mail: Sally_Foust@ccgate.depuy.com

TRADE NAME: DePuy Duraloc® Acetabular Cup System – Enduron
Liner

COMMON NAME: Hip Cup Liner

CLASSIFICATION: 888. .3358 – Hip joint metal/polymer semi-constrained
cementless prosthesis

DEVICE PRODUCT CODE: 87 LPH and JDM

SUBSTANTIALLY EQUIVALENT DEVICE:

Modified DePuy Acetabular Cup System (K900832)
Modified AML® + Acetabular Cup Prosthesis
(K900891)
DePuy Duraloc® Cementless Acetabular Cup System
(K961186)

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Duraloc Acetabular Liners are manufactured from ultra high molecular weight polyethylene (UHMWPE) and are available in two designs, standard and Charnley Bore (CB). Both designs are available in two styles, a neutral and 10° lip, with an inner diameter (I.D.) of 22.225mm and are available in sizes to fit Duraloc metal acetabular shells with outer diameters of 48mm-74mm. The Duraloc liners are locked into the Duraloc metal acetabular shells with a metal wire locking ring supplied with the shells.

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

BASIS OF SUBSTANTIAL EQUIVALENCE:

The intended use as described in its labeling, fundamental scientific technology, and material of the 22.225mm I.D. UHMWPE liners of the DePuy Duraloc Acetabular Cup System has not changed from the cleared (K900832, K900891, and K961186) 22.225mm, 26mm, 28mm and 32mm I.D. UHMWPE liners of the DePuy Duraloc Acetabular Cup System.

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The standard liners are identical in design to the previously cleared (K900832, K900891) DePuy Duraloc acetabular cup liners except for the smaller (22.225mm) inner diameter. The standard liners are also identical in design to the previously cleared (K961186) DePuy Duraloc Bantam acetabular cup liners except the subject liners are available in larger sizes to fit Duraloc metal acetabular shells with outer diameters of 48mm-74mm.

The Charnley Bore (CB) liners are identical in design to the previously cleared (K900832, K900891) DePuy Duraloc acetabular cup liners except for the smaller (22.225mm) inner diameter and the additional 2mm of polyethylene added on the face of the liner wall. The Charnley Bore (CB) liners are also identical in design to the previously cleared (K961186) DePuy Duraloc Bantam acetabular cup liners except that the subject liners are available in larger sizes to fit Duraloc metal acetabular shells with outer diameters of 48-74mm and have an additional 2mm of polyethylene added on the face of the liner wall.

Based on similarities of design, material and intended use, DePuy believes that the subject DePuy Duraloc Acetabular Liners are substantially equivalent to the cleared liners of the DePuy Duraloc Acetabular Cup System.

Refer to the following table for a summary of the similarities:

	Current Submission	Modified DePuy Acetabular Cup System	Modified AML Acetabular Cup Prosthesis	DePuy Duraloc Cementless Acetabular Cup System
		K900832	K900891	K961186
Materials	UHMWPE ASTM F-648	UHMWPE ASTM F-648	UHMWPE ASTM F-648	UHMWPE ASTM F-648
Inner Diameters	22.225mm	26, 28 and 32mm	26, 28 and 32mm	22.225, 26 and 28mm
Outer Diameters	48-74mm	46-74mm	46-74mm	38-46mm
Design	Standard and Charnley Bore (CB)	Standard	Standard	Standard
Lip	Neutral and 10°	Neutral, 10° and 20°	Neutral, 10° and 20°	10°
Locking Mechanism	Metal Wire Ring	Metal Wire Ring	Metal Wire Ring	Metal Wire Ring

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sally Foust
Regulatory Submissions Associate
DePuy, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581-0988

Re: K983491
Trade Name: DePuy Duraloc® Acetabular
Cup System Euduron Liner
Regulatory Class: II
Product Codes: LPH and JDM
Dated: October 2, 1998
Received: October 5, 1998

Dear Ms. Foust:

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.

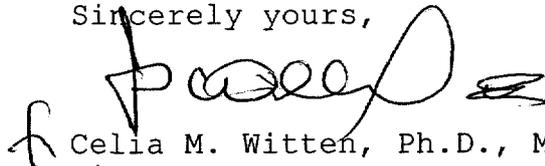
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,


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) K983491

Device Name: DePuy Duraloc Acetabular Cup Liners: Additional Liners

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation

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



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983491