

FEB 3 2000

K 994415

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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 Marathon™ Cross-linked Polyethylene Acetabular Cup Liners

COMMON NAME: Acetabular Cup Prosthesis

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

DEVICE PRODUCT CODE: 87 LPH

SUBSTANTIALLY EQUIVALENT DEVICES: DePuy Duraloc Acetabular Cup Liners

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Marathon Cross-linked Polyethylene Acetabular Cup Liners are UHMWPE acetabular cup liners that are available with 28mm or 32mm inner diameters and with a neutral or 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 52-80mm. The polyethylene liners are locked into the Duraloc metal shells with a metal wire locking ring which is supplied with the metal shells.

The Marathon Acetabular Cup Liners are manufactured from UHMWPE that has been cross-linked by exposure to radiation in a very low oxygen environment and then heat treated prior to machining of the liners. The cross-linked polyethylene has physical and mechanical properties that are similar to those of standard UHMWPE but has increased resistance to oxidation and wear. Marathon cross-linked UHMWPE meets all of the specifications of ASTM F648.

The DePuy Marathon Cross-linked Polyethylene 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.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Marathon Cross-linked Polyethylene Acetabular Cup Liners have the following similarities to the acetabular cup liners that were cleared in K972596: same intended use; same material; same method of manufacture; same design; same mating components; same sterilization and packaging methods.

DePuy is now adding a labeling claim for reduced wear. This claim is supported by 10 million cycle hip simulator wear data which show that when tested against highly polished femoral balls, the acetabular

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cups manufactured from Marathon cross-linked UHMWPE, (with and without artificial aging) exhibit 85-86% less wear than identical acetabular cups manufactured from conventional UHMWPE. When tested against moderately roughened femoral heads the Marathon cross-linked cups wore 74-79% less than the conventional UHMWPE cups and when tested against severely roughened femoral heads the Marathon cross-linked cups wore 17-56% less than the conventional UHMWPE cups. These in vitro results have not been correlated to clinical experience.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994415
Trade Name: Marathon Cross-linked Polyethylene Acetabular Cup Liners
Regulatory Class: II
Product Code: LPH
Dated: January 13, 2000
Received: January 14, 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 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

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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) 594-4595. 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 James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) 994415

Device Name DePuy Marathon Cross-linked Polyethylene Acetabular Cup Liners

Indications for Use:

The DePuy Marathon Cross-linked Polyethylene 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 K974415

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use

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