

OCT 5 1998

K982585

SUMMARY OF SAFETY AND EFFECTIVENESS

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

510(k) CONTACT: Sally Foust
Sr.Regulatory Submissions Associate
(219) 372-7455; FAX (219) 267-7098

TRADE NAME: DePuy AMK® Total Knee System
DePuy Coordinate Ultra™ Knee Revision System

COMMON NAME: Knee Device

CLASSIFICATION: 888.3560 Prosthesis, Knee, PatelloFemorotibial,
Semiconstrained, Cemented, Polymer, Metal, Polymer

DEVICE PRODUCT CODE: 87 JWH

SUBSTANTIALLY EQUIVALENT DEVICES:

- (DePuy) Anatomic Modular Knee (AMK) System (K864671)
- (DePuy)Anatomic Modular Knee (AMK) Polyethylene Tibial Tray (K910940)
- (DePuy) AMK Polyethylene Posterior Stabilized Tibial Tray (K943299)
- (DePuy) AMK Congruency Posterior Stabilized Insert (K954684)
- (DePuy) Coordinate II (Ultra) Knee Revision System (K955884)
- (DePuy) Duraloc Acetabular Cup System (K972596)

DEVICE DESCRIPTION AND INTENDED USE:

The subject DePuy AMK and Coordinate Ultra cross-linked polyethylene tibial inserts and trays are available in five sizes (1-5) with five thickness' (10, 12, 14, 16, and 18mm) or ten thickness' (10, 12, 14, 16, 18, 20, 22, 24, 26, and 28mm), depending on the specific device, in each size. The cross-linked polyethylene tibial inserts fasten to a metal tibial tray by means of a central pin and interlocking clip or a tibial stabilizing post. The fixative surface of the cross-linked polyethylene tibial trays have a salt-blasted surface, a round central stem, and cloverleaf patterned recesses to enhance cement fixation to the proximal tibia surface. The DePuy AMK and Coordinate Ultra cross-linked polyethylene tibial inserts and trays are intended to be used with the currently legally marketed DePuy AMK Total Knee System and/or Coordinate Ultra Knee Revision System in cemented tricompartmental total knee arthroplasty to replace severely disabled or painful joints resulting from osteoarthritis or post-traumatic arthritis, joints with correctable varus or valgus deformity, and joints with failed previous surgeries where pain, deformity or dysfunction persist.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject DePuy AMK and Coordinate cross-linked polyethylene tibial inserts and trays are substantially equivalent to the AMK Total Knee System and Coordinate Ultra Knee Revision System polyethylene tibial inserts and trays that have previously been cleared in that they have the basic same design and the same intended use. Both the subject cross-linked polyethylene tibial inserts and trays and the previously cleared polyethylene tibial inserts and trays are manufactured from UHMWPE meeting the specifications of ASTM F648. The only difference, other than minor design changes, between the subject components and the previously cleared components is that the subject components are manufactured from cross-linked UHMWPE.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982585
DePuy AMK® Total Knee System and Coordinate Ultra™ Knee
Revision System: Cross-Linked Polyethylene Tibial
Inserts and Trays
Regulatory Class: II
Product Code: JWH
Dated: July 23, 1998
Received: July 24, 1998

Dear Ms. Foust:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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). This decision is based on these devices being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your devices subject to the general controls provisions of the Act and the following limitations:

1. The thinnest tibial insert available is the nominal "10mm" sized insert, which has a minimum polyethylene thickness under the condyles of 6.02mm.
2. The thinnest tibial tray available is the nominal "10mm" sized tray, which has a minimum polyethylene thickness under the condyles of 10.5mm.
3. These devices may not be labeled or promoted for non-cemented use.
4. All labeling for these devices, including package label and labeling included within the package, must

prominently state that the devices are intended for cemented use only.

5. Any non-cemented fixation of these devices is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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.

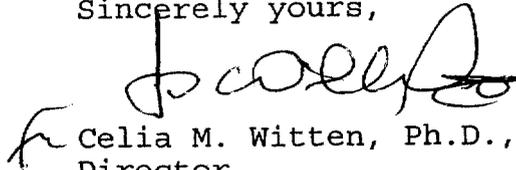
This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, please contact the Office of Compliance at (301) 594-4639. Also, please note

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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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke at the end.

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

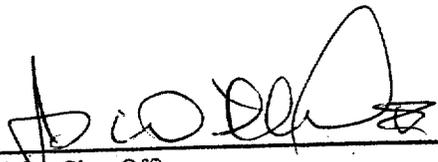
510(k) Number (if known) K982585

Device Name: DePuy AMK® Total Knee System and Coordinate Ultra™ Knee Revision System: Cross-Linked Polyethylene Tibial Inserts and Trays

Indications for Use:

The DePuy AMK and Coordinate Ultra Cross-Linked Polyethylene Inserts and Trays are to be used with the currently marketed AMK Total Knee System and/or the Coordinate Ultra Knee Revision System components.

The DePuy AMK Total Knee System and Coordinate Ultra Knee Revision System are intended to be used in cemented tricompartmental total knee arthroplasty to replace severely disabled or painful joints resulting from osteoarthritis or post-traumatic arthritis, joints with correctable varus or valgus deformity, and joints with failed previous surgeries where pain, deformity or dysfunction persist.



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982585

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X

OR
(Per 21 CFR 801.109)

Over-The Counter Use _____

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