

K97 2643

JAN 21 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

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

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

TRADE NAME: DePuy AMK 3 Peg Patella

COMMON NAME: All Polyethylene Patella

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

DEVICE PRODUCT CODE: 87 JWH

**SUBSTANTIALLY
EQUIVALENT DEVICES:**

- ❖ DePuy AMK All Polyethylene Patella
- ❖ DePuy LCS 3 Peg Patella
- ❖ Johnson & Johnson PFC Oval Sombrero Patella
- ❖ Zimmer NexGen All Polyethylene Patella

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy AMK 3 Peg Patella is an all polyethylene patella component with a domed articular surface and a 3 peg fixation surface. It is intended for use with the DePuy AMK Total Knee System for cemented, tricompartmental total knee arthroplasty, utilizing the AMK system's existing femoral components, tibial trays, and tibial inserts. The AMK system is intended 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 DePuy AMK 3 Peg Patella is identical to the AMK All Polyethylene Patella which has been previously cleared by FDA except that the fixation surface has been changed from two circular arcs to 3 pegs. The material, intended use and design of the articular surface of the patella are the same as those of the original AMK All Polyethylene Patella. The 3 peg fixation surface is similar to the fixation surface used on the DePuy LCS All Polyethylene 3 Peg Patella. Testing indicates that the fixation strength of the AMK 3 Peg Patella is similar to those of the Johnson & Johnson PFC Oval Sombrero Patella and the Zimmer NexGen All Polyethylene Patella.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1998

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

Re: K972643
AMK 3 Peg Patella
Regulatory Class: II
Product Code: JWH
Dated: December 17, 1997
Received: December 19, 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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

3. Any non-cemented fixation of this device 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 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.

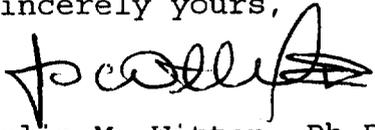
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

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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,


fm 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

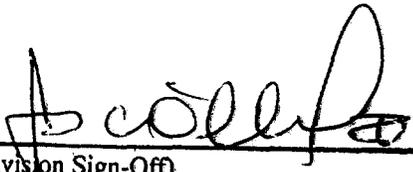
510(k) Number (if known) K972643

Device Name AMK 3 Peg Patella

Indications for Use:

The DePuy AMK 3 Peg Patella is intended for use with the DePuy AMK Total Knee System for cemented, tricompartmental total knee arthroplasty, utilizing the AMK system's existing femoral components, tibial trays, and tibial inserts. The AMK system is intended 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.

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972643

Prescription Use X

OR

Over-The Counter Use _____

(Per 21 CFR 801.109)

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