

MAR 18 1998

K97 4740

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

**510(K) CONTACT:** Arlene C. Saull, RAC  
Sr. Submissions Associate  
DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
Warsaw, IN 46581-0988

**TRADE NAME:** DePuy Tri-Lock Hip Stem

**COMMON NAME:** Porous-coated hip prosthesis

**CLASSIFICATION:** Class II per 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

**DEVICE PRODUCT CODE:** 87 LPH: Prosthesis, Hip, Semi-Constrained Metal/Polymer, Porous Uncemented

**SUBSTANTIALLY EQUIVALENT DEVICES:** DePuy Prodigy Hip  
DePuy AML Proximally-Coated Stem,  
DePuy Porocoat Dual Lock Total Hip System,

**DEVICE DESCRIPTION AND INTENDED USE:**

The DePuy Tri-Lock Hip Stem consists of variously sized femoral hip stems which will be available in two versions (standard and lateralized) with a modular head design. The DePuy Tri-Lock Hip Stem employs Porocoat porous coating for use with or without cement. When it is used cementless, it is intended for tissue ingrowth to obtain biological fixation.

The DePuy Tri-Lock Hip Stem is indicated for cementless use in the treatment of:

1. A severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis;
2. Avascular necrosis of the femoral head;
3. Acute traumatic fracture of the femoral head or neck;
4. Failed previous surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement;
5. Certain cases of ankylosis.

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**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The DePuy Tri-Lock Hip Stem is similar in material and intended use (cementless) to the Prodigy Hip and the AML Proximally-Coated Hip Stem, both cleared for cementless use.

The subject DePuy Tri-Lock Hip Stem is similar in material, design and size to the predicate Tri-Lock Hip Stem, (submitted as the DePuy Porocoat Dual Lock Total Hip System) which was cleared for cemented use.

All of these systems consist of ASTM F-75 Cast Cobalt Chromium Molybdenum Alloy femoral stems with porous coating made from ASTM F-75 Cobalt Chromium Molybdenum Alloy. All of the predicate modular femoral stems have identical neck tapers that use the DePuy Articul/eze Total Hip Balls, available in Cobalt Chrome and Zirconia Ceramic.

Based on the information supplied in this premarket notification submission, DePuy, Inc. believes that the subject Tri-Lock Hip Stem is substantially equivalent in terms of materials, design, sizing and intended use to the Prodigy Hip, AML Proximally-Coated Stem, and the Porocoat Dual Lock Total Hip System (predicate Tri-Lock) that have been previously cleared by the FDA. It is expected that the performance of the subject DePuy Tri-Lock Hip Stem will be similar to these predicate devices.

Arlene C. Saull  
Arlene C. Saull, RAC  
Sr. Submissions Associate

12-18-97  
Date

END OF 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FORM



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 18 1998

Ms. Arlene C. Saull  
Senior Submissions Associates  
DePuy Inc.  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

Re: K974740  
Trade Name: DePuy Tri-Lock® Hip Stem  
Regulatory Class: II  
Product Code: LPH  
Dated: December 18, 1997  
Received: December 19, 1997

Dear Ms. Saull:

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 (Pre-market 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 pre-market 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,



*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

## INDICATIONS

510(k) Number (if known) \_\_\_\_\_

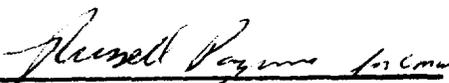
Device Name DePuy Tri-Lock® Hip Stem

Indications for Use:

The DePuy Tri-Lock Hip Stem is indicated for cementless use in the treatment of:

1. A severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis;
2. Avascular necrosis of the femoral head;
3. Acute traumatic fracture of the femoral head or neck;
4. Failed previous surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement;
5. Certain cases of ankylosis.

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Concurrence of CDRH, Office of Device Evaluation:

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K974740

Prescription Use X

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

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