

OCT 19 2001

K012364

**510(k) Summary**

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**Name of Sponsor:**

**DePuy Orthopaedics, Inc.**  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988  
Est. Reg. No. 1818910

**510(k) Contact:**

**Marcia J. Arentz**  
Senior Regulatory Associate  
Phone: (219) 371-4944  
FAX: (219) 371-4987

**Trade Name:**

**AML<sup>®</sup> Hip Prosthesis**

**Common Name:**

Total Hip Joint Replacement Prosthesis with porous coating

**Classification:**

**Class II Device per 21 CFR 888.3358:**  
Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis

**Device Product Code:**

Code: **87LPH** Prosthesis Hip Semi-constrained, Metal/Polymer, Porous Uncemented  
No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.

**Substantially Equivalent Device:**

Porocoat<sup>®</sup> Prodigy<sup>™</sup> Hip Prosthesis **K931641**  
Vision AML<sup>®</sup> Hip Prosthesis **K953694**  
AML Hip Prosthesis **K003800**

**Device Descriptions:**

The AML hip stem is manufactured from ASTM F-75 Cobalt-Chromium-Molybdenum alloy and has a sintered cobalt-chrome-molybdenum alloy bead porous coating (Porocoat<sup>®</sup>) applied to the stem. The porous coating is applied to the entire stem with the exception of the tapered stem tip region.

**Intended use:**

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

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## 510(k) Summary (continued)

### Indications for use:

Total hip replacement is indicated in the following conditions:

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

### Substantial equivalence:

Based on similarities of design, commonly used materials, identical sterilization processes, the same indications for use and intended use, DePuy believes that the modified AML Hip Prosthesis is substantially equivalent to the FDA-cleared Prodigy Hip Prosthesis system, the Vision AML Hip System and the AML Hip Prosthesis.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Marcia J. Arentz  
Senior Regulatory Associate  
DePuy, Inc.  
P.O. Box 988  
700 Orthopedic Drive  
Warsaw, Indiana 46581-0988

Re: K012364  
Trade Name: AML Hip Prosthesis  
Regulation Number: 21 CFR 888.3358, 21 CFR 888.3350  
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous  
Coated Uncemented Prosthesis and Hip Joint  
Metal/Polymer/Metal Semi-Constrained Cemented Prosthesis  
Regulatory Class: Class II  
Product Code: LPH, JDI  
Dated: July 24, 2001  
Received: July 26, 2001

Dear Ms. Arentz:

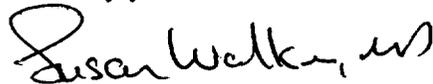
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K012364

Device Name: **AML Hip Prosthesis**

**Indications for Use:**

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

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

The AML<sup>®</sup> Hip Stem is indicated for cementless use and fixation by biological tissue ingrowth into the porous coating as well as cemented use and fixation in which the porous coating serves as a means to augment the fixation of the prostheses to the bone cement.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use Yes  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

for Mark N. Millman  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K012364

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