MAY 20 1998

K980794

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

DePuy®

**NAME OF FIRM:**

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

**DePuy Inc.**
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Warsaw, Indiana 46581-0988
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Telephone: + 1 (219) 267 8143
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**510(K) CONTACT:**

Arlene C. Saull, RAC
Sr. Submissions Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
Phone: 219-372-7176

**TRADE NAME:** Dual Lock® Hip Stem

**COMMON NAME:** Cemented hip prosthesis

**CLASSIFICATION:** Class II per 888.3350: Hip joint, metal/polymer semi-constrained cemented prosthesis

**DEVICE PRODUCT CODE:** 87 JDI: Prosthesis, Hip, Semi-Constrained Metal/Polymer, Cemented

**SUBSTANTIALLY EQUIVALENT DEVICES:**
DePuy Prodigy Hip
DePuy Cemented Hip Prosthesis
DePuy Porocoat Dual Lock Total Hip System

**DEVICE DESCRIPTION AND INTENDED USE:**
The Dual Lock Hip Stem system consists of variously sized femoral hip stems made from Cobalt Chrome which will be available with standard and lateral offsets. The Dual Lock Hip Stems are designed with neck tapers intended to be used with DePuy femoral ball heads made from Cobalt Chrome or Zirconia Ceramic, and DePuy acetabular components with ultra high molecular weight polyethylene articulating surfaces.

The Dual Lock Hip Stem is intended for use as the cemented femoral component in total hip arthroplasty for 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.

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

## BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject Dual Lock Hip Stem is similar in material (Cobalt Chrome), design, sizing, and intended use (with cement) to the DePuy Porocoat Dual Lock Total Hip System previously cleared by FDA for cemented use, except the subject device does not employ porous coating on the stem. The modular neck taper of the subject Dual Lock Hip Stem is identical to the DePuy Prodigy Hip, also previously cleared via 510(k). They are both intended for use with the same DePuy femoral hip balls which are legally marketed devices. The offsets available with the subject device are similar to those of the DePuy Cemented Hip Prosthesis which was previously cleared via 510(k).

Based on the information supplied in this premarket notification submission, DePuy believes that the subject Dual Lock Hip Stem is substantially equivalent in terms of materials, design, sizing and intended use to the predicate DePuy Porocoat Dual Lock Total Hip System, the DePuy Prodigy Hip, and the DePuy Cemented Hip Prosthesis (all cleared via 510(k)). It is expected that the performance of the subject DePuy Dual Lock Hip Stem will be similar to these predicate devices.

Signature: Arlene C. Saull Date: February 26, 1998

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Arlene C. Saull, RAC
Senior Submissions Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K980794
Trade Name: Dual Lock® Hip Stem
Regulatory Class: II
Product Code: JDI
Dated: February 27, 1998
Received: March 2, 1998

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 (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 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) 980794

Device Name Dual Lock® Hip Stem

Indications for Use:

The Dual Lock Hip Stem is indicated for use as the cemented femoral component in total hip arthroplasty for 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 K980794

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