NOV 0 7 2001

510(k) Summary K013350

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) 371-4940
Trade Name:	**DePuy C-Stem™ System**
Common Name:	Total Hip Joint Replacement Prosthesis
Classification:	**Class II** Device per 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis
Device Product Code:	Code: **87JDI** No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.
Substantially Equivalent Device:	DePuy C-Stem System K982918
Device Descriptions:	The DePuy C-Stem System hip stem is a collarless, slim-profiled, triple-tapered polished stem manufactured from stainless steel. The C-Stem system also includes an end cap made from either gelatin or PMMA and PMMA centralizers.
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.
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 facture 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:

The fundamental scientific technology of the C-Stem System has not changed from the FDA cleared DePuy C-Stem System described in K982918. The intended use and indications for use have not changed The material from which the additional end cap is manufactured has been changed to PMMA, the same material used to manufacture other legally marketed end cap devices.

Based on conformance with the design control procedures requirements as specified in 21 CFR 820.30, similarities of design, the same indications for use and intended use, DePuy believes that the C-Stem end cap to be substantially equivalent to the FDA cleared C-Stem System originally cleared in K982918.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K013350
Trade Name: DePuy C-Stem™ System
Regulation Number: 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: October 5, 2001
Received: October 9, 2001

Dear Ms. Arentz :

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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.

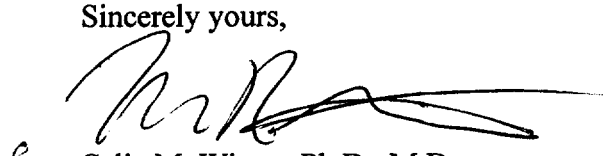
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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,



for 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

NOV 0 7 2001

K013350

510(k) Number (if known): K013350

Device Name: DePuy C-Stem™ System

Indications for Use:

The DePuy C-Stem System is indicated for cemented use as the femoral component in total hip arthroplasty.

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.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013350

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