

OCT 5 1998

K982918

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR OF THIS 510(K): DePuy, Inc.
P.O. Box 988
Warsaw, Indiana 46581-0988

510(K) CONTACT: Sally Foust
DePuy Orthopaedics, Inc.
Sr. Regulatory Submissions Associate
(219) 372-7455; FAX (219) 267-7098

TRADE NAME: DePuy C-Stem™ System

COMMON NAME: Hip prosthesis

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

DEVICE CODE: JDI

EQUIVALENT DEVICES: CPT Hip Prosthesis (K960658)
Exeter Total Hip System (K974054, K980843)
Ortron 90* Hip Prosthesis (Charnely) (K802627)
DePuy Elite Hip (K871867)
BIOSTOP® G Bone Cement Restrictor (K943727)
DePuy Distal Stem Centralizers (K951930)

DEVICE DESCRIPTION AND INTENDED USE:

The subject DePuy C-Stem System includes stainless steel femoral stems, a gelatin end cap and PMMA centralizers. The C-Stem is a collarless, slim profiled, triple-tapered, and overall polished stem that is available in four stem designs. The four stem designs are: a CDH stem available in one size; a primary stem available in eight sizes (1, 2, 3, 4, 5, 6, 7; and 8); a high offset stem available in three sizes (3, 4, and 5); and a revision stem available in three sizes (4, 6, and 8) each of which is available in two lengths (200mm and 240mm).

The DePuy C-Stem System is indicated for cemented use as the femoral component in total hip arthroplasty for replacing the hip joint of a patient with a severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; failed previous surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and certain cases of ankylosis.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject C-Stem System is identical in material and intended use to the FDA cleared Elite and Chanley hip stems in that the stems are manufactured from Ortron stainless steel and are intended

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for cemented use as the femoral component in total hip arthroplasty. The subject C-Stem System is similar in material, design, and intended use to the FDA cleared Exeter Total Hip System in that the stems are manufactured from stainless steel, collarless, slim profiled, polished, and are intended for cemented use as the femoral component in total hip arthroplasty in which femoral canal centering devices are used (i.e., end caps, centralizers). The subject C-Stem System is similar in design and intended use to the FDA cleared CPT Hip Prosthesis in that the stems are collarless, slim-profiled, polished and are intended for cemented use as the femoral component in total hip arthroplasty in which femoral canal centering devices are used. All materials used to manufacture the subject C-Stem System's components (stems, end cap, and centralizers) are also those used to manufacture the referenced FDA cleared orthopaedic devices.

Based on similarities of design, materials and intended use, DePuy believes that the subject C-Stem System is substantially equivalent to the FDA cleared CPT, Exeter, Elite and Charnley Hip Systems.

The following table summarizes the similarities:

	C-STEM	CPT	EXETER	ELITE	CHARNLEY
Material	Ortron Stainless Steel	Cobalt- Chrome	316L Stainless Steel	Ortron Stainless Steel	Ortron Stainless Steel
Use	Cemented	Cemented	Cemented	Cemented	Cemented
Design	Collarless Slim Profile Three Tapers Polished	Collarless Slim Profile Two Tapers Polished	Collarless Slim Profile Two Tapers Polished	Collarless Slim Profile Two Tapers Textured	Collorless Slim Profile Two-Tapers Textured
Modular Heads	Yes	Yes	Yes	Yes	No
EndCaps/ Centralizers/ Cement Restrictors	Yes	Yes	Yes	Yes	Yes

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 1998

Ms. Sally Foust
Senior Regulatory Submissions Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K982918
Trade Name: DePuy C-Stem™ System
Regulatory Class: II
Product Codes: JDI, LZO, and LZN
Dated: August 18, 1998
Received: August 19, 1998

Dear Ms. Foust:

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.

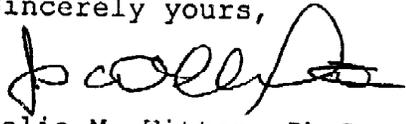
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,

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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

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510(k) Number (if known) K982918

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 for replacing the hip joint of a patient with a severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; failed previous surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and certain cases of ankylosis.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982918

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