K042959

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DEC 22 2004

DePuy
a Johnson & Johnson company

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

DATE PREPARED: 20 October 2004

SPONSOR OF 510(k):
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive, Warsaw, IN 46581-0988
Establishment Registration Number: 1818910

510(K) CONTACT:
Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
Tel: (574) 371-4905, Fax: (574) 371-4987
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TRADE NAME: DePuy® C-Stem AMT Hip Prosthesis
COMMON NAME: Total Hip Joint Replacement Prosthesis
CLASSIFICATION: Class II per CFR 888.3350 (JDI)
Hip joint metal/polymer semi-constrained cemented prosthesis
Unclassified (LZO)
Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented
DEVICE PRODUCT CODE: 87JDI or 87LZO
SUBSTANTIALLY EQUIVALENT DEVICES: C-stem (K982918) cleared October 12, 1998
Titan hip (K001991) cleared August 31, 2000

DEVICE DESCRIPTION:
The C-Stem AMT hip is a collarless, tapered, press-fit femoral stem. It is manufactured from wrought stainless steel (Ortron 90® conforming to ISO 5832-9) and is polished overall. The stem is offered in 7 sizes, with each body size having either a standard or high offset. It may be used with commercially available modular femoral heads, either metal or ceramic, to form the femoral component of a total hip prosthesis. Accessory items include previously cleared cement restrictors and centralizers.

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 DePuy® C-Stem AMT Hip Stem is indicated for cemented use only.

SUBSTANTIAL EQUIVALENCE:
Neither the intended use nor the fundamental scientific technologies of the DePuy® C-Stem AMT have changed from the legally marketed predicate devices, the DePuy Titan Porocoat® Hip Prosthesis (K001991) and the DePuy C-Stem System (K982918). They have the same material, intended use, indications, sterilization method, packaging and method of manufacture. The design, while not identical to the predicates, does not raise any new issues of safety or effectiveness. DePuy believes that the DePuy® C-Stem AMT is substantially equivalent to these two previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2004

Ms. Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K042959
Trade/Device Name: C-Stem AMT Hip Prosthesis
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI, LZO
Dated: November 19, 2004
Received: November 22, 2004

Dear Ms. Weissman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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

Indications for Use

510(k) Number (if known): K042959
Device Name: DePuy® C-Stem AMT Hip Stem

Indications for Use:

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Prescription Use XXXXXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K042959