

K082239 # 1/2

AUG 29 2008

510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

NAME OF SPONSOR: DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582
Establishment Registration Number: 1818910

510(K) CONTACT: Rhonda Myer
Regulatory Affairs Associate
Telephone: (574) 371-4927
Facsimile: (574) 371-4987
Electronic Mail: Rmyer7@dpyus.jnj.com

DATE PREPARED: July 24, 2008

PROPRIETARY NAME: DePuy C-Stem AMT

COMMON NAME: Cemented hip stem prosthesis

CLASSIFICATION: Class III per 21 CFR 888.3330: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (KWA)

Class II per 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis (JDI)

Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (LZO)

Class II per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (LPH)

DEVICE PRODUCT CODE: 87 KWA, JDI, LZO, LPH

SUBSTANTIALLY EQUIVALENT DEVICE: DePuy C-Stem AMT, K042959

DEVICE DESCRIPTION:

The C-Stem AMT hip is a collarless, tapered, cemented femoral stem. It may be used with commercially available modular femoral heads, either metal or ceramic, to form the

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femoral component of a total hip prosthesis to articulate against either a metal or poly insert.

INDICATIONS AND INTENDED USE:

Indications:

The DePuy C-Stem AMT is indicated for cemented use in the treatment of:

1. A severely painful and/or a severely disabled joint resulting 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 surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and
5. Certain cases of ankylosis.

Intended Use:

The subject C-Stem AMT is intended for cemented use as part of the femoral component in a total hip arthroplasty.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Based on the similarities in intended use, indications for use, materials, design, method of manufacture, sterilization and packaging methods, DePuy believes the subject C-Stem AMT is substantially equivalent to the previously cleared DePuy C-Stem AMT, K042959.



AUG 29 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Rhonda Myer
Regulatory Affairs Associate
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K082239

Trade/Device Name: DePuy C-Stem AMT
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA, JDI, LZO, LPH
Dated: August 6, 2008
Received: August 7, 2008

Dear Ms. Myer:

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

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number (if known): K082239

Device Name: DePuy C-Stem AMT

Indications for Use:

The DePuy C-Stem AMT is indicated for cemented use in the treatment of:

1. A severely painful and/or a severely disabled joint resulting 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 surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and
5. Certain cases of ankylosis.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)



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

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