K071830

SEP 28 2007

Section 5 – 510 (k) Summary

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations and the Safe Medical Devices Act of 1990.

LABELED MANUFACTURER AND SPONSOR OF 510(K) SUBMISSION:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration Number: 1818910
CONTRACT MANUFACTURER:	CERAMTEC AG Fabrikstr. 23-29 Plochingen, GERMANY 73207 Establishment Registration Number: 8044172
510(K) CONTACT:	Rhonda Myer, Regulatory Affairs Associate Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: RMyer7@dpyus.jnj.com
510(K) PREPARER:	Rebecca Lennard Independent Contractor Electronic Mail: RLennard@dpyus.jnj.com
DATE PREPARED:	April 19, 2007
PROPRIETARY NAME:	DePuy Delta TS Ceramic Femoral Head
COMMON NAME:	Ceramic Femoral Head Prosthesis
CLASSIFICATION:	Class II Device per 21 CFR 888.3353: Hip joint femoral metal/ceramic/polymer, semi-constrained cemented or nonporous, uncemented prosthesis
DEVICE PRODUCT CODE:	87 LZO
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Femoral Heads, K011533 DePuy Ceramic Femoral Heads, K031803 DePuy Ceramic Heads, K040644 Universal Taper Delta Femoral Head, K070885 V-40™/C-Taper Adapter Sleeve, K051737 V-40™ BIOLOX® delta Ceramic Femoral Heads, K052718

DEVICE DESCRIPTION:

The DePuy Delta TS (Taper Sleeve) Ceramic Femoral Heads are designed for use as the femoral head component in total hip arthroplasty procedures. The femoral head is manufactured from an alumina composite ceramic material and includes an internal titanium alloy sleeve to mate with DePuy femoral hip stems with a corresponding taper. The ceramic femoral head mechanically locks with the femoral hip stem via a taper junction, and articulates with a polyethylene acetabular component.

The subject DePuy Delta TS Ceramic Femoral Heads are available in femoral head outer diameters of 28mm, 32mm, 36mm, 40mm and 44mm. The internal bore of the titanium sleeve is available in a 12/14 option.

INTENDED USE AND INDICATIONS FOR USE:

Intended Use:

The DePuy Delta TS Ceramic Femoral Head is intended for use in total hip arthroplasty applications to replace the articular surface of the femoral head in primary hip surgery and for the salvage of a failed previous hip surgery.

Indications for Use:

The DePuy Delta TS Ceramic Hip Head Prosthesis is indicated for use as the femoral head component in total hip arthroplasty procedures.

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.

BASIS OF SUBSTANIAL EQUIVALENCE:

The DePuy Delta TS Ceramic Femoral Heads described in this submission are substantially equivalent to the predicate devices based on similarities in intended use and

design. In addition, the material, manufacturing methods, packaging and sterilization of the predicate devices and the subject device are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Rhonda Myer
Regulatory Affairs Associate
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

SEP 2 8 2007

Re: K071830
Trade/Device Name: DePuy Delta TS Ceramic Femoral Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint femoral metal/ceramic/polymer, semi-constrained cemented or nonporous, uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: July 2, 2007
Received: July 3, 2007

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.

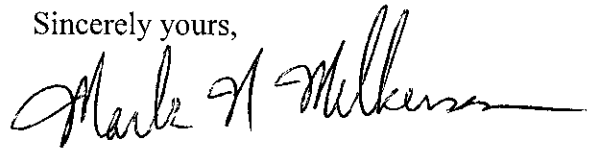
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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

Section 4 – Indications for Use Statement

510 (k) Number (if known): K071830

Device Name: DePuy Delta TS Ceramic Femoral Heads

Indications for Use:

The DePuy Delta TS Ceramic Hip Head Prosthesis is indicated for use as the femoral head component in total hip arthroplasty procedures.

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.

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

Mark N Milhous

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

510(k) Number K071830