

**510(k) Summary of Safety and Effectiveness**

K062748

**NAME OF FIRM:** DePuy Orthopaedics, Inc.  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, IN 46581-0988

**510(k) CONTACT:** Anne M. Schuler  
Sr. Regulatory Affairs Associate

**DATE PREPARED:** September 13, 2006

**TRADE NAME:** DePuy Delta Ceramic Femoral Head

**COMMON NAME:** Ceramic Femoral Ball Prosthesis

**CLASSIFICATION:** 888.3353: Hip joint femoral metal/ceramic/polymer, semi-constrained cemented or nonporous, uncemented prosthesis;

**DEVICE PRODUCT CODE:** 87 LZO

**SUBSTANTIALLY EQUIVALENT DEVICE:** DePuy Ceramic Femoral Heads, K031803  
DePuy Ceramic Heads, K040644

**DEVICE DESCRIPTION:**

The DePuy Delta Ceramic Femoral Head is composed of an alumina composite material and is available in a 36mm head diameter with +9 and +12 offset options. The internal bore of the ceramic femoral head taper is available in an 11/13 S-ROM option.

The Delta Ceramic head is designed to mate with DePuy femoral hip stems with a corresponding taper design. The ceramic femoral head mechanically locks with the femoral hip stem via a taper junction, and articulates with a polyethylene acetabular component.

**INDICATIONS FOR USE AND INTENDED USE:****Indications for Use**

The DePuy Ceramic Femoral Head 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 to 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.

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### **Intended Use**

The DePuy Ceramic Femoral Head is intended for use in total hip arthroplasty applications to replace the articular surface of the femoral head.

### **BASIS OF SUBSTANTIAL EQUIVALENCE:**

The modified DePuy Delta Ceramic femoral heads have a similar design and the same intended use, indications, manufacturing method, sterilization and packaging as the Ceramic Femoral heads cleared in K031803 and in K040644. Based on this DePuy believes that the subject Delta Ceramic femoral heads are substantially equivalent to the previously cleared Ceramic femoral heads.

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DePuy Orthopaedics, Inc.  
% Ms. Anne M. Schuler  
Sr. Regulatory Affairs Associate  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 30 2006

Re: K062748

Trade/Device Name: DePuy Delta Ceramic Femoral Head

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Regulatory Class: Class II

Product Code: LZO

Dated: September 13, 2006

Received: November 6, 2006

Dear Ms. Schuler:

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.

Page 2 – Ms. Anne M. Schuler

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a large initial "M" and a long, sweeping tail.

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

510(k) Number (if known): K062748  
Device Name: DePuy Delta Ceramic Femoral Head

### Indications for Use:

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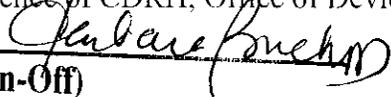
Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

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5. Certain cases of ankylosis.

Prescription Use XX 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  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K062748