K082585 pg 1/2

DEC 0 4 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@its.jnj.com
Manufacturer:	DePuy International St. Anthony's Road Beeston Leeds United Kingdom LS11 8DT
Contract Sterilizer:	Swann-Morton Ltd. Owlerton Green Sheffield S6 2BJ United Kingdom
Date Prepared:	December 2, 2008
Proprietary Name:	DePuy aSphere M-Spec Head
Common Name:	Modular Femoral Head
Classification:	Class III per 21 CFR 888.3330: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis Class II per 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis Class II per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Product Codes:	87 KWA, 87 JDI, and 87 LPH
Substantially Equivalent Devices:	**DePuy M-Spec Head** **36 mm:** K980513 and internal documentation to K851422 **40 mm and 44 mm**: K060031

Device Description:

The aSphere M-Spec Head is part of a modular prosthesis system for use in total hip replacement. It mates with DePuy femoral stems and articulates with DePuy acetabular inserts and cups.

Indications for Use:

The DePuy aSphere M-Spec Head is indicated for 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 arthoplasty, or other total hip replacement; and
5. Certain cases of ankylosis.

Intended Use:

The subject aSphere M-Spec Head is intended for 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 aSphere M-Spec Head is substantially equivalent to the previously cleared DePuy M-Spec Head, cleared in K980513, internal documentation to K851422, and K060031.

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 Dr.
Warsaw, Indiana 46581

DEC 0 4 2008

Re: K082585
Trade/Device Name: DePuy aSpehere M-Spec Head
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, LPH
Dated: November 5, 2008
Received: November 6, 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.

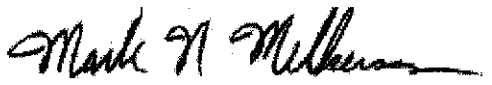
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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): K082585 (pg 1/1)

Device Name: DePuy aSphere M-Spec Head

Indications for Use:

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1. A severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis, or congenital hip dysplasia;
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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)

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

510(k) Number K082585