K082715

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DEC 18 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
MANUFACTURER:	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
PROPRIETARY NAME:	DePuy Global AP CTA Humeral Head
COMMON NAME:	Shoulder Prosthesis, Humeral Head
CLASSIFICATION:	**Class II** device per 21 CFR §888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (HSD)
DEVICE PRODUCT CODE:	**87 HSD** Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Global Advantage Extended Head, K000575

DEVICE DESCRIPTION:

The Global AP CTA Humeral Head, in combination with a Global AP Shoulder humeral stem, is intended for use in hemi-shoulder arthroplasty.

INDICATIONS AND INTENDED USE:

Indications:

The Global AP CTA Humeral Head, used with a Global AP Humeral Stem, is indicated for use in hemi-shoulder replacement.

Hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures.
2. Avascular necrosis of the humeral head.
3. Rotator cuff tear arthropathy.
4. Deformity and/or limited motion.

Un-coated Global AP Humeral Stems are indicated for cemented use only. Global AP Humeral Stems with Porocoat® are indicated for cemented or cementless use.

Intended Use:

The Global AP CTA Humeral Head, in combination with a Global AP Shoulder humeral stem, is intended for use in hemi-shoulder 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 Global AP CTA Humeral Head is substantially equivalent to the previously cleared Global Advantage Extended Head, K000575.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K082715
Trade/Device Name: DePuy Global AP CTA Head
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: HSD
Dated: December 3, 2008
Received: December 4, 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 (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 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

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

Enclosure

K082715

Indications for Use Statement

510 (k) Number (if known): K082715

Device Name: DePuy Global AP CTA Head

Indications for Use:

The Global AP CTA Humeral Head, used with a Global AP Humeral Stem, is indicated for use in hemi-shoulder replacement.

Hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
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Prescription Use __X__ (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)

(Posted November ~~12, 2008~~)

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

510(k) Number K082715