K080990

510(k) Summary

AUG - 8 2008

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

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration Number: 1818910
MANUFACTURER:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration Number: 1818910
510(K) CONTACT:	Dawn Sinclair Regulatory Affairs Associate Telephone: (574) 372-5023 Facsimile: (574) 371-4987 Electronic Mail: Dsincla3@dpyus.jnj.com
DATE PREPARED:	March 17, 2008
PROPRIETARY NAME:	DePuy Global C.A.P.™ CTA Resurfacing Shoulder
COMMON NAME:	Resurfacing Shoulder
CLASSIFICATION:	Class II per 21 *CFR* 888.3690, Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
DEVICE PRODUCT CODE:	87HSD
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy Global Advantage® Extended Humeral Head, K000575 Copeland™ EAS Humeral Resurfacing Heads, K051843 DVO™ Total Extended Articulation Humeral Heads, K073331 DePuy Global C.A.P.™ Resurfacing Replacement Shoulder, K031971 Copeland™ MB/HA Resurfacing Humeral Heads, K010827

DEVICE DESCRIPTION:

The DePuy Global C.A.P.™ CTA Resurfacing Shoulder is a conservative Cuff Tear Arthropathy (CTA) device designed for resurfacing of the humeral head (hemi-shoulder). Resurfacing requires less bone and cartilage removal than is required in total shoulder replacement. Because bone stock is preserved, future revision or arthrodesis can be more easily performed. The prosthesis is intended for uncemented (i.e., press-fit) fixation, and is designed to mimic the normal humeral head geometry.

Composed of a cobalt-chrome-molybdenum alloy (ASTM F-75), the DePuy Global C.A.P.™ CTA Resurfacing Shoulder is available in a variety of diameters. The proposed implant will be available in curvatures of 40, 44, 48, 52 and 56mm, with head heights of 15mm (40 and 44mm curvatures), 18mm (all curvatures) or 21mm (48, 52 and 56mm curvatures).

The proposed humeral head is a one-piece shell, manufactured from cobalt-chrome-molybdenum alloy (ASTM F-75). The inner surface of the dome, or humeral head, has a cobalt-chrome-molybdenum porous coating. The stem has a cobalt-chrome-molybdenum porous coating proximally and is glass bead blasted distally. The distal stem has a cruciate design with a tapered distal tip. A thin layer of plasma-sprayed hydroxyapatite (Duofix™) has been applied to the inner surface of the dome and proximal stem.

The hydroxyapatite (HA) coating applied to the DePuy Global C.A.P.™ CTA Resurfacing Shoulder is substantially equivalent to the HA coating process used in previously cleared products (e.g., DePuy Global C.A.P.™ Resurfacing Replacement Shoulder, K031971; DePuy Global C.A.P.™ HA Resurfacing Shoulder Humeral Heads, K033516). The composition of the coating is the same as that used for previously cleared products, (e.g., DePuy Global C.A.P.™ Resurfacing Replacement Shoulder, K031971; DePuy Global CAP™ HA Resurfacing Shoulder Humeral Heads, K033516).

The DePuy Global C.A.P.™ CTA Resurfacing Shoulder features an extended articulation surface to cover the superior-lateral aspect of the resurfacing head. This additional material keeps the implant surface in contact with the coracoacromial arch for a longer period of time during abduction.

This device also features a stem with a distal cruciate press fit to provide initial fixation. For long-term fixation and implant support, a surface-to-surface contact between the underside of the cup and the humeral head is created because of a flat located on the underside of the cup. Fixation is also provided by biological tissue in-growth into the porous coating.

INTENDED USE AND INDICATIONS FOR USE:

Intended Use:

The DePuy Global C.A.P.™ CTA Resurfacing Shoulder prosthesis is intended for use in hemi-shoulder arthroplasty.

Indications for Use:

The DePuy Global C.A.P.™ CTA Resurfacing Shoulder is indicated for hemi-shoulder replacement in patients with rotator cuff tears and arthritis. Specific indications include:

1. Rotator cuff tear arthropathy.
2. Difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate.

CAUTION: The DePuy Global C.A.P.™ CTA Resurfacing Shoulder is intended for cementless use only.

BASIS OF SUBSTANTIAL EQUIVALENCE

The DePuy Global C.A.P.™ CTA Resurfacing Shoulder described in this submission is, in our opinion, substantially equivalent to the previously cleared DePuy Global Advantage® Extended Humeral Head (K000575), the Copeland™ EAS Humeral Resurfacing Heads (K051843), the DVO™ Total Extended Articulation Humeral Heads (K073331), the DePuy Global C.A.P.™ Resurfacing Shoulder (K031971), and the Copeland™ MB/HA Resurfacing Humeral Heads (K010827), based upon the similarities in design, material composition (cobalt-chrome-molybdenum alloy), methods of sterilization (gamma irradiation) and intended use/indications for use. The subject device does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG - 8 2008

Re: K080990
Trade/Device Name: DePuy Global C.A.P.™ CTA Resurfacing Shoulder
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: June 18, 2008
Received: June 19, 2008

Dear Ms. Sinclair:

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
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): K080990

Device Name: DePuy Global C.A.P.™ CTA. Resurfacing Shoulder

Indications for Use:

The DePuy Global C.A.P.™ CTA Resurfacing Shoulder is indicated for hemi-shoulder replacement in patients with rotator cuff tears and arthritis. Specific indications include:

1. Rotator cuff tear arthropathy.
2. Difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate.

CAUTION: The DePuy Global C.A.P.™ CTA Resurfacing Shoulder is intended for cementless use only.

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

Barbara Frechette

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

510(k) Number K080990