DEC - 3 2003

K033516

510(k) Summary

NAME OF SPONSOR:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(K) CONTACT:	**Tiffani D. Rogers** Regulatory Associate Phone: (574) 371-4927 FAX: (574) 371-4987
TRADE NAME:	**DePuy Global CAP™ HA Resurfacing Shoulder Humeral Heads**
COMMON NAME:	Resurfacing Shoulder
CLASSIFICATION:	**Class II** Device per 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
DEVICE PRODUCT CODE:	**HSD**
SUBSTANTIALLY EQUIVALENT DEVICES:	**Humeral Head:** DePuy Global CAP Resurfacing Replacement Shoulder, K031971

DEVICE DESCRIPTION:

The DePuy Global CAP™ HA Resurfacing Shoulder Humeral Heads are composed of a cobalt chrome molybdenum alloy (ASTM F-75), and are available in a variety of diameters. This device will be available in curvatures of 40, 44, 48, 52 and 56mm, all available with head heights of 15mm (short), 18mm (medium) or 21mm (large) (**Exhibit 1**). This proposed range of sizes is designed to fit the natural range of the humeral head anatomy. This range and combination of head diameters and head heights have been cleared in the Global Advantage Humeral Head Premarket Notification (K031971). The stem is a tapered cruciate design intended to provide maximum fixation and stability when impacted in the humerus.

The humeral head is a one-piece shell with 2mm thick wall. The stem has a cobalt chrome porous coating proximally and is grit blasted distally. The distal stem has a cruciate design and tapers down to the distal tip. The distal tip has a 58° radius. A thin layer of plasma sprayed hydroxyapatite (HA) has been applied to the humeral heads.

K033516

510(k) Summary (cont.)

INTENDED USE AND INDICATIONS:
The DePuy Global CAP™ HA Resurfacing Shoulder Humeral Heads are intended as a hemi or total shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable. This device is designed to increase shoulder mobility by: reducing pain; restoring alignment; restoring flexion and extension movement; and resisting dislocation.

The DePuy Global CAP™ HA Resurfacing Shoulder Humeral Heads are indicated for use as a replacement of shoulder joints disabled by rheumatoid arthritis with pain, non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis), deformity and/or limited motion, fractures of the humeral head and traumatic arthritis.

The DePuy Global CAP™ HA Resurfacing Shoulder Humeral Heads are intended for cementless use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Based on similarities of design, materials, sterilization processes and the same intended use, DePuy believes that the Global CAP™ HA Resurfacing Shoulder Humeral Heads are substantially equivalent to the previously cleared Global CAP Resurfacing Replacement Shoulder, K031971.

DePuy believes the hydroxyapatite (HA) coating applied to the Global CAP™ HA Resurfacing Shoulder Humeral Heads is substantially equivalent to the HA coating process used in previously cleared products. The composition of the coating is the same as that used for previously cleared products, i.e. Triflange acetabular cup system (K001277). However, the Global CAP™ HA Resurfacing Shoulder Humeral Heads features a HA coating applied to a Cobalt Chrome porous coating while all other products consists of a HA coating on Titanium. Characterization data for the HA coating on Cobalt Chrome is provided in **Exhibit 4**. Process specifications for the application of a HA coating to Titanium have been provided previously in Master File MAF 339.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 2003

Ms. Tiffani D. Rogers
Regulatory Affairs Associate
DePuy Orthopedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K033516
Trade/Device Name: Global CAP™ HA Resurfacing Shoulder Humeral Heads
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: HSD
Dated: November 5, 2003
Received: November 7, 2003

Dear Ms. Rogers:

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 Office of Compliance at (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033516

Device Name: Global CAP™ HA Resurfacing Shoulder Humeral Heads

Indications for Use:

The DePuy Global CAP™ HA Resurfacing Shoulder Humeral Heads are intended as a hemi or total shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable. This device is designed to increase shoulder mobility by: reducing pain; restoring alignment; restoring flexion and extension movement; and resisting dislocation.

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CAUTION: The DePuy Global CAP™ HA Resurfacing Shoulder Humeral Heads are intended for cementless use only.

Concurrence of CDRH, Office of Device Evaluation

for Mark N Milhous

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

510(k) Number K033516

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

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