K050315

1 of 2

MAY 16 2005

510(k) Summary

NAME OF SPONSOR:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
MANUFACTURER:	**DePuy France S.A.** Z I La Vendue BP88 Chaumont 52003 France Est. Reg. No. 9615674
510(K) CONTACT:	Natalie S. Heck Manager, Regulatory Affairs Phone: (574) 372-7469 FAX: (574) 371-4987
TRADE NAME:	**Delta CTA™ Humeral Cups**
COMMON NAME:	Shoulder Prosthesis
CLASSIFICATION:	**Class II** Device per 21 CFR 888.3660: Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
DEVICE PRODUCT CODE:	**87 KWS**
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Delta Shoulder, K021478

DEVICE DESCRIPTION:

The Delta CTA™ Humeral Cups proposed in this submission are a line extension to the humeral cup system components cleared in the DePuy Delta CTA™ Shoulder submission (cleared as DePuy Delta Shoulder under K021478, November 18, 2003). The additional humeral cups are made of polyethylene and will be available in four sizes: 36mm diameter + 3mm thickness, 36mm diameter + 9mm thickness, 42mm diameter + 3mm thickness and 42mm diameter + 9mm thickness.

510(k) Summary (cont.)

INTENDED USE AND INDICATIONS:
The Delta CTA™ Humeral Cups, as part of the DePuy Delta CTA™ Total Shoulder are intended for use in patients with non-functional rotator cuffs with or without bone cement.

The Delta CTA™ Total Shoulder Prosthesis is indicated for use in grossly rotator cuff deficient joint with severe arthropathy or a previous failed joint replacement with a grossly rotator cuff deficient joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional Deltoid muscle is necessary to use the device.

The metaglene component is HA coated and is intended for cementless application with the addition of screws for fixation. All other components are intended for cemented use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:
DePuy believes the humeral cups proposed in this submission are substantially equivalent to the humeral cups cleared in the previous DePuy Delta CTA™ Total Shoulder Prosthesis submission. The design, material and manufacturing method of the humeral cups is identical to those cleared in K021478 (cleared November 18, 2003), however the range of sizes of available cups will be increased to 36mm diameter + 3mm thickness, 36mm diameter + 9mm thickness, 42mm diameter + 3mm thickness and 42mm diameter + 9mm thickness. Currently, humeral cups compatible with the Delta CTA™ Total Shoulder prosthesis are available in 36mm diameters in +0mm and + 6mm thicknesses, and 42mm diameters in +0mm and + 6mm thicknesses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2005

Ms. Tiffani D. Rogers
DePuy Orthopaedics Incorporated
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K050315
Trade/Device Name: Delta CTA™ Humeral Cups
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: April 15, 2005
Received: April 20, 2005

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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting 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): K050315

Device Name: Delta CTA™ Humeral Cups

Indications for Use:

A Delta Total shoulder prosthesis is indicated for use in:

Grossly rotator cuff deficient joint with severe arthropathy or a previous failed joint replacement with a grossly rotator cuff deficient joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional Deltoid muscle is neoessary to use the device.

The metaglene component is HA coated and is intended for cementless application with the addition of screws for fixation. All other components are intended for cemented use only.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K050315