

K062250

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Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations and the Safe Medical Devices Act of 1990.

510 (k) Summary

NAME OF SPONSOR: DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Establishment Registration Number: 1818910

510(K) CONTACT: Natalie Heck
Manager, Regulatory Affairs
Telephone: (574) 372-7469
Facsimile: (574) 371-4987
Electronic Mail: nheck@dpvus.inj.com

DATE PREPARED: July 26, 2006

PROPRIETARY NAME: Delta Xtend™ Reverse Shoulder System

COMMON NAME: Shoulder Prosthesis

CLASSIFICATION: Class II Device per 21 CFR 888.3660:
Prosthesis, Shoulder, Semi-Constrained,
Metal/Polymer Cemented
Class II Device per 21 CFR §888.3690:
Prosthesis, Shoulder, Hemi-, Humeral, Metallic
Uncemented

DEVICE PRODUCT CODE: 87 KWS
87 HSD

**SUBSTANTIALLY EQUIVALENT
DEVICE:** DePuy Delta CTA Reverse Shoulder System,
K021478
DePuy Global Advantage Shoulder System,
K992065
DePuy Global Advantage CTA Head (cleared as
the DePuy Global Advantage Extended Head)
K000575

DEVICE DESCRIPTION:

The Delta Xtend™ Reverse Shoulder System is a modular shoulder prosthesis designed for use in patients with non-functional rotator cuffs.

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INTENDED USE AND INDICATIONS:**Intended Use:**

The Delta Xtend™ Reverse Shoulder prosthesis is intended for use in total or hemi shoulder arthroplasty procedures in patients with non-functional rotator cuffs.

Indications for Use:

The Delta Xtend™ Reverse Shoulder prosthesis is intended for use as total shoulder or hemi-shoulder replacement.

Delta Xtend™ Reverse Shoulder prosthesis is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff 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.

In cases of bone defects in the proximal humerus, the monobloc implant should be used and then only in cases where the residual bone permits firm fixation of this implant.

Delta Xtend™ hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively.

The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation.

All other components are for cemented use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of the Delta Xtend™ Reverse Shoulder is substantiated by its similarity in intended use, indications for use, materials and design to the DePuy Delta CTA Reverse Shoulder System (K021478), the DePuy Delta CTA Head (K062116), the DePuy Global Advantage Shoulder System (K992065), and the DePuy Global Advantage CTA Head (K000575, cleared as the DePuy Global Advantage Extended Head).



DePuy Orthopaedics, Inc.
c/o Ms. Natalie Heck
Manager, Regulatory Affairs
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K062250

Trade Name: Delta Xtend™ Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: December 4, 2006
Received: December 6, 2006

Dear Ms. Heck:

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.

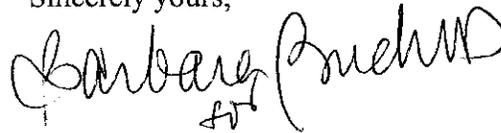
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Natalie Heck

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

Mark N. Melkerson, M.S.

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): K062250

Device Name: Delta Xtend™ Reverse Shoulder System

Indications for Use:

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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.

In cases of bone defects in the proximal humerus, the monobloc implant should be used and then only in cases where the residual bone permits firm fixation of this implant.

Delta Xtend™ hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively.

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All other components are for cemented use only.

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

Barbara Bruehl
(Division Sign-Off)
November 13, 2003

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**Division of General, Restorative,
and Neurological Devices**

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