DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

DePuy Orthopaedics, Incorporated
Ms. Rhonda Myer
Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46581

Re: K081620
Trade/Device Name: DePuy 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: PHX, KWS, HSD
Dated: June 6, 2008
Received: June 9, 2008

Dear Ms. Myer:

This letter corrects our substantially equivalent letter of June 30, 2008.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081620

## Indications for Use Statement

510 (k) Number (if known): _____

Device Name: DePuy Delta Xtend Reverse Shoulder System

**Indications for Use:**

The 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 or for revision of a previously failed Delta Xtend Reverse Shoulder.

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

The modular humeral stem and epiphysis components are HA coated and intended for cementless use.

All other components are for cemented use only.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Page 1 of 1

Division of General, Restorative, and Neurological Devices

510(k) Number K081620

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JUN 30 2008

## 510 (k) Summary

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

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|---|---|
| **NAME OF SPONSOR:** | DePuy Orthopaedics, Inc.<br>700 Orthopaedic Drive<br>Warsaw, Indiana 46582<br>Establishment Registration Number: 1818910 |
| **MANUFACTURER:** | DePuy France SAS<br>7 Allée Irène Joliot Curie<br>69801 Saint Priest Cedex France<br>Establishment Registration: 3003895575 |
| **510(K) CONTACT:** | Rhonda Myer<br>Regulatory Affairs Associate<br>Telephone: (574) 371-4927<br>Facsimile: (574) 371-4987<br>Electronic Mail: Rmyer7@dpyus.jnj.com |
| **DATE PREPARED:** | June 4, 2008 |
| **PROPRIETARY NAME:** | DePuy Delta Xtend Reverse Shoulder System |
| **COMMON NAME:** | Shoulder Prosthesis |
| **CLASSIFICATION:** | Class II per 21 CFR 888.3660: Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented |
| **DEVICE PRODUCT CODE:** | 87 KWS<br>87 HSD |
| **SUBSTANTIALLY EQUIVALENT DEVICE:** | DePuy Delta Xtend Reverse Shoulder System, K062250 and K073676 |

**DEVICE DESCRIPTION:**

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

**INDICATIONS AND INTENDED USE:**

**Indications:**
The 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 or for revision of a previously failed Delta Xtend Reverse Shoulder.

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

The modular humeral stem and epiphysis components are HA coated and intended for cementless use.

All other components are for cemented use only.

**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, with or without bone cement. HA coated components are for cementless use only.

**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 Delta Xtend Reverse Shoulder System is substantially equivalent to the previously cleared Delta Xtend Reverse Shoulder System, K062250 and K073676.