DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

DePuy Orthopaedics
Ms. Megan Burns
Associate, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46580

Re: K122442
Trade/Device Name: DePuy Delta CTA™ 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
Dated: August 9, 2012
Received: August 10, 2012

Dear Ms. Burns:

This letter corrects our substantially equivalent letter of September 6, 2012.

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

K122442 (1/1)

Section 4: Indications for Use Statement

510 (k) Number (if known): _____

Device Name: **DePuy Delta CTA™ Reverse Shoulder System**

Indications for Use:

A Delta CTA™ Reverse 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. **For US Use Only:** 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122442

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K122442 (1/2)

SEP 6 2012

Section 5: 510(k) Summary

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

Submitter Information	
Name	DePuy Orthopaedics
Address	700 Orthopedic Drive
Phone number	574-372-7745
Fax number	574- 371-4987
Establishment Registration	1818910
Name of contact person	Megan Burns
Date prepared	August 9, 2012
Name of device	
Trade or proprietary name	Delta CTA™ Reverse Shoulder System
Common or usual name	Shoulder Prosthesis
Class	II
Classification panel	87 - Orthopedics
Regulation	21 CFR 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis
Product Code(s)	KWS
Legally marketed device(s) to which equivalence is claimed	Delta CTA™ Reverse Shoulder System – Humeral Cups (K050315, cleared May 16, 2005)
Reason for 510(k) submission	Line Extension
Device description	The Delta CTA™ Reverse Shoulder is DePuy's first generation reverse shoulder system. In a reverse shoulder, the articulation is "inverted" compared to traditional, anatomical total shoulder prosthesis so that the "ball" of the articulation is incorporated into the glenoid prosthesis and the "cup" of the articulation is incorporated into the humeral prosthesis. This inverted design helps stabilize a shoulder in the absence of a functional rotator cuff.
Intended use of the device	Reverse Shoulder Arthroplasty
Indications for use	A Delta CTA™ Reverse 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. **For US Use Only:** All other components are intended for cemented use only.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
CHARACTERISTICS	**Subject Device:** **DePuy DELTA CTA™ Hybrid Humeral cups**	**Predicate Device:** **DePuy DELTA CTA™ Humeral cups (K050315)**
Intended Use	Reverse Shoulder Arthroplasty	SAME
Indications for Use	A Delta CTA™ Reverse 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. **For US Use Only:** All other components are intended for cemented use only.	SAME
Material	UHWMPE	SAME
Sizes	**Diameters:** 38 mm and 42mm **Thickness:** +3mm, +6mm, +9mm	**Diameters:** 36mm and 42mm **Thickness:** +3mm and +9mm

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
Stack analyses demonstrated the subject device to be compatible with the existing mating components (Delta CTA epiphysis and Delta Xtend glenospheres).		

COMPARATIVE PERFORMANCE INFORMATION SUMMARY

Characteristic	Requirement	New Device	Predicate Device
The results of the non-clinical testing demonstrate substantial equivalence to the predicate.			

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The results of the non-clinical testing demonstrate substantial equivalence to the predicate.