May 17, 2019

DePuy (Ireland)
% Yayoi Fujimaki
Regulatory Affairs Project Manager
DePuy Orthopaedics, Inc.
700 Orthopaedic Dr.
Warsaw, Indiana 46582

Re: K183077
Trade/Device 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: PHX, KWS, HSD
Dated: April 17, 2019
Received: April 18, 2019

Dear Yayoi Fujimaki:

This letter corrects our substantially equivalent letter of May 17, 2019.

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FOR CAPT Raquel Peat, PhD, MPH, USPHS
Director
DHT6A: Division of Joint Arthroplasty Devices
OHT 6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183077

Device Name
DELTA XTEND Reverse Shoulder System

Indications for Use *(Describe)*
The Delta Xtend Shoulder Prosthesis is indicated for use in treatment of a grossly deficient rotator cuff joint with:
• severe arthropathy and/or;
• a previously failed joint replacement and/or:
• fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory

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.

Delta Xtend hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively or for the 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 humeral epiphysis components are HA coated and intended for cementless use.

All other metallic components are intended for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

As required by 21 CFR 807.92 and 21 CFR 807.93

Submission Information		
Sponsor Name	DePuy (Ireland)	
Sponsor Address	Loughbeg, Ringaskiddy Co. Cork Ireland	
Sponsor Establishment Registration Number	9616671	
510(k) Contact	Yayoi Fujimaki DePuy Synthes Regulatory Project Manager	Phone: 508.828.3541 Email: yfujima1@its.jnj.com
Date prepared	November 2, 2018	
Device Information		
Trade or proprietary name	DELTA XTEND™ Reverse Shoulder System	
Common or usual name	Shoulder Prosthesis	
Classification name	Shoulder joint metal/polymer semi-constrained cemented prosthesis	
Class, regulation	Class II, 21 CFR 888.3660	
Product Code	PHX, KWS, HSD	
Classification panel	Orthopedics panel	
Legally marketed device(s) to which equivalence is claimed	DELTA XTEND Reverse Shoulder System (DePuy: K062250, K120174), Aequalis Reversed Prosthesis (Tornier SAS: K030941, K061439, K081059, K140478, K151293)	
Reason for 510(k) submission	Addition of lateralized glenosphere components to the Delta Xtend Reverse Shoulder System	
Device description	The Delta Xtend Reverse Shoulder System consists of humeral stem, modular epiphysis, humeral spacer, humeral cup, glenosphere, metaglene and metaglene screws. The glenosphere and metaglene are used for total reverse shoulder arthroplasty. The humeral spacer can be added between the epiphysis and the humeral cup if necessary. Humeral head can be used in hemi-shoulder arthroplasty in place of the humeral cup and glenoid components.	
Intended use of the device	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.	
Indications for use	The Delta Xtend Shoulder Prosthesis is indicated for use in treatment of a grossly deficient rotator cuff joint with: • severe arthropathy and/or; • a previously failed joint replacement and/or: • fracture-dislocations of the proximal humerus where the	

	articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory 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. Delta Xtend hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively or for the 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 humeral epiphysis components are HA coated and intended for cementless use. All other metallic components are intended for cemented use only.
Testing Data	
Summary of non-clinical study	Biocompatibility was confirmed per ISO10993-1. Theoretical simulated range of motion analyses showed increase of range of motion compared to the predicate non-lateralized glenosphere. Glenoid loosening/disassociation study demonstrated substantial equivalency of glenoid fixation performance to the predicate.
Summary of animal study	Animal study was not necessary.
Summary of clinical study	Clinical study was not necessary.
Conclusion	Substantial equivalency to the predicate devices can be demonstrated on following grounds: - the subject lateralized glenosphere has the same intended use as the predicate glenosphere of the Delta Xtend Reverse shoulder system and the Aequalis Reversed Shoulder Prosthesis. - the subject lateralized glenosphere's technological characteristics are equivalent to the predicate Aequalis Reversed Shoulder Prosthesis glenosphere. - different technological characteristic between the subject and the predicate Delta Xtend Reverse Shoulder System is glenosphere lateralization. Addition of the lateralized glenosphere does not change the intended use, indications, principle of operation or surgical procedure. No new question is raised. Performance study demonstrated substantial equivalency to the predicate. Therefore, the subject Delta Xtend lateralized glenosphere is substantially equivalent to the predicate Delta Xtend Reverse shoulder system. The design, intended use, and materials are also equivalent to the Tornier Aequalis Reversed Shoulder Prosthesis

	(K151293, K140478, K081059, K061439, K030941).

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES		
Device	Subject Device: Delta Xtend Reverse Shoulder System Lateralized glenosphere	Predicate: Delta Xtend Reverse Shoulder System Glenosphere
510(k)#	This submission (DePuy)	K062250, K120174 (DePuy)
Intended Use	Reverse Shoulder Arthroplasty	Reverse Shoulder Arthroplasty
Glenosphere Material		
Body	CoCrMo alloy	CoCrMo alloy
Fixation component	Titanium alloy	Titanium alloy
Glenosphere Design		
Sizes	38, 42mm	38, 42mm
Sphere	Centered, eccentric (2mm)	Centered, eccentric (2mm)
Lateralization	0, 2, 4, 6, 8mm	0mm
Fixation with base plate	Taper lock and screw	Taper lock and screw
Others		
Sterilization	Gamma, single use	Gamma, single use
Shelf Life	5 years	5 years