February 24, 2020

DePuy (Ireland)
% Ashley Goncalo
Project Manager - Regulatory Affairs
Depuy Orthopaedics, Inc
325 Paramount Drive
RAYNHAM MA 02767

Re: K192855
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
Dated: January 23, 2020
Received: January 24, 2020

Dear Ashley Goncalo:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Michael Owens
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: 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)*

K192855

Device Name
DELTA XTEND™ Reverse Shoulder System

Indications for Use *(Describe)*

The DELTA XTEND Prosthesis is indicated for use in treatment of a grossly deficient rotator cuff joint with:
• severe arthropathy and/or;
• a previous failed joint replacement and/or;
• Fracture-dislocations of the proximal humerus where the articular surface is severely communited, 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. Porous-coated epiphysis are indicated for use in total shoulder replacement only.

The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation. The modular humeral stem is HA coated and is intended for cementless use. The HA coated humeral epiphysis is intended for cementless use. The porous-coated epiphysis is intended for cemented or 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	Ashley Goncalo DePuy Synthes Regulatory Project Manager	Phone: 508.977.3907 Email: agoncalo@its.jnj.com
Date prepared	10/2/2019	
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	
Classification panel	Orthopedics panel	
Legally marketed device(s) to which equivalence is claimed	Predicates: DePuy Synthes GLOBAL UNITE Platform Shoulder System (K170748) and DELTA XTEND Reverse Shoulder System (K071379, K120174) Reference Device: Tornier Aequalis™ Ascend™ Flex Shoulder System (K122698)	
Reason for 510(k) submission	Line extension to DELTA XTEND Reverse Shoulder System to add additional epiphysis device components. Additionally, this submission supports the addition of MRI compatibility language to the labeling for the currently marketed, FDA cleared, DELTA XTEND Reverse Shoulder System and GLOBAL UNITE Platform 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 used for 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 Prosthesis is indicated for use in treatment of a grossly deficient rotator cuff joint with: • severe arthropathy and/or; • a previous failed joint replacement and/or; • Fracture-dislocations of the proximal humerus where the articular surface is severely communited, 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. Porous-coated epiphysis are indicated for use in total shoulder replacement only. The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation. The modular humeral stem is HA coated and is intended for cementless use. The HA coated humeral epiphysis is intended for cementless use. The porous-coated epiphysis is intended for cemented or cementless use. All other metallic components are intended for cemented use only.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES				
Characteristic	**Subject Device: Epiphysis Device - DELTA XTEND™ Reverse Shoulder System**	**Primary Predicate Device: Epiphysis Device - DePuy Synthes GLOBAL UNITE Platform Shoulder System (reverse configuration) (K170748)**	**Predicate Device: Epiphysis Device - DELTA XTEND™ Reverse Shoulder System (K071379, K120174)**	**Reference Device: Epiphysis Device - Tornier Aequalis™ Ascend™ Flex Shoulder System (reverse configuration) (K122698)**
Intended Use	Reverse shoulder arthroplasty	Reverse shoulder arthroplasty	Reverse shoulder arthroplasty	Reverse shoulder arthroplasty
Material				
Epiphysis Component	Titanium alloy with Porocoat® porous-coating	Titanium alloy with Porocoat® porous-coating	Titanium alloy with hydroxyapatite coating	Titanium alloy with titanium plasma spray coating
Screw Component	Titanium alloy	Titanium alloy	Titanium alloy	N/A
Design				
Modularity	Epiphysis component interfaces with stem component via male-female boss and screw	Epiphysis component interfaces with stem component via male-female boss and screw	Epiphysis component interfaces with stem component via male-female boss and screw	Stem component (unified epiphysis and diaphysis) interfaces with reversed tray component
Neck Shaft Angle	145° and 155°	155°	155°	145°

Epiphysis Sizes	Size 1 and 2 (in centered, eccentric left and eccentric right versions)	Size 1 (in centered, eccentric left and eccentric right versions)	Size 1 and 2 (in centered, eccentric left and eccentric right versions)	N/A

PERFORMANCE DATA

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

The proposed Epiphysis Device of the DELTA XTEND Reverse Shoulder System was determined as substantially equivalent in terms of safety and efficacy with the predicate devices as demonstrated by the following:

- Fatigue Analysis
- Tolerance Analysis
- Epiphysis Comparison and Design Justification
- Range of Motion Analysis
- Biocompatibility Study
- The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI AAMI ST-72:2011.

Additionally, MRI testing was conducted in support of adding MRI compatibility language for the currently marketed shoulder platforms, with which the proposed devices are compatible – the existing DELTA XTEND Reverse Shoulder System and GLOBAL UNITE Shoulder System.

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 proposed epiphysis device of the DELTA XTEND Reverse Shoulder System is substantially equivalent to the epiphysis devices of the predicate DePuy Synthes GLOBAL UNITE Platform Shoulder System and predicate DELTA XTEND Reverse Shoulder System.