DePuy Ireland UC
℅ Jaclyn Cincotta
Regulatory Project Manager
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

July 22, 2021

Re: K203694
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: June 23, 2021
Received: June 24, 2021

Dear Jaclyn Cincotta:

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
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)*

K203694

Device Name
DELTA XTEND Reverse Shoulder System

Indications for Use *(Describe)*

The DePuy Synthes DELTA XTEND™ Shoulder 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 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. Porous-coated epiphysis are indicated for use in total shoulder replacement only.

The metaglene component is either HA coated or porous-coated and is intended for cementless use with the addition of screws for fixation. Central screws can only be used with the porous-coated metaglenes and are required to be used with porous-coating augmented metaglenes.

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.

510(k) Summary

As required by 21 CFR 807.92 and 21 CFR 807.93

Submitter Information	
Sponsor Name	DePuy Ireland UC
Sponsor Address	Loughbeg Ringaskiddy Co. Cork Ireland
Sponsor Establishment Registration Number	9616671
510(k) Contact	Jaclyn Cincotta Regulatory Affairs Project Manager Telephone: (508) 828-3269 Fax: (508) 977-6409 Email: jcincott@its.jnj.com Address: 700 Orthopaedic Drive, Warsaw, IN 46582, USA
Date Prepared	22 July 2021
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	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3660
Product Code(s)	PHX, KWS
Legally Marketed Device(s) to Which Equivalence is Claimed	Predicate Devices: DePuy Synthes DELTA XTEND Reverse Shoulder System (K120174, K192855) and Tornier Aequalis PerFORM Reversed and Aequalis PerFORM+ Reversed Glenoid Shoulder Prosthesis (K161742, K183696) Reference Device: DePuy Synthes GLOBAL UNITE Platform Shoulder System (K170748)
Reason for 510(k) Submission	Line extension to the DePuy Synthes DELTA XTEND Reverse Shoulder System to add additional metaglene and metaglene screw devices.

Device Description	The DELTA XTEND Reverse Shoulder System consists of humeral stems, modular epiphysis, humeral spacers, humeral cups, glenospheres, metaglenes and metaglene screws used for reverse shoulder arthroplasty. Humeral heads can be used in hemi-shoulder arthroplasty in place of the humeral cup and glenoid components. The metaglenes are available in various design configurations including standard and augmented designs. The metaglenes allow for the placement of a central screw down the center of the post. A separate collet component is inserted into the metaglene post to receive the locking screw of the glenospheres.
Intended Use of the Device	The DELTA XTEND Reverse Shoulder System is intended for use in total or hemi-shoulder arthroplasty 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 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 either HA coated or porous-coated and is intended for cementless use with the addition of screws for fixation. Central screws can only be used with the porous-coated metaglenes and are required to be used with porous-coated augmented metaglenes. 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.
Comparison of Technological Characteristics with the Predicate Device	The DELTA XTEND Reverse Shoulder System has the same intended use and the same fundamental scientific technology as the predicate devices. The standard metaglenes are similar to those of the DePuy Synthes DELTA XTEND Reverse Shoulder System (K120174) and the augmented metaglenes and central screws are similar to those of the Tornier Aequalis PerFORM Reversed and Aequalis PerFORM+ Reversed Glenoid Shoulder Prosthesis (K161742, K183696). The porous-coating of the subject metaglene devices is similar to the DELTA XTEND Reverse Shoulder System (epiphysis devices) (K192855) and reference device DePuy Synthes GLOBAL UNITE Platform Shoulder System (reverse epiphysis devices) (K170748).

Performance Data	The following tests were performed on the subject devices of the DELTA XTEND Reverse Shoulder System to demonstrate substantial equivalence of safety and efficacy with the predicate devices: • Pullout Evaluation • Fatigue Evaluation • Micromotion Evaluation • Taper Dissociation Evaluation • Torque to Failure Evaluation • Insertion Force Evaluation • Range of Motion Evaluation • MRI Compatibility Evaluation
Clinical Data	No clinical studies were required to demonstrate substantial equivalence.
Conclusion	The subject devices of the DELTA XTEND Reverse Shoulder System are substantially equivalent to the metaglene/baseplate and screw devices of the predicate DePuy Synthes DELTA XTEND Reverse Shoulder System (K120174, K192855) and the Tornier Aequalis PerFORM Reversed and Aequalis PerFORM+ Reversed Glenoid Shoulder System (K161742, K183696).