January 11, 2018

DePuy Ireland UC
% Kellie Myers
Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Dr.
Warsaw, Indiana 46582

Re: K170748
Trade/Device Name: GLOBAL UNITE Platform 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: January 3, 2018
Received: January 4, 2018

Dear Kellie Myers:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170748

Device Name
GLOBAL UNITE Platform Shoulder System

Indications for Use *(Describe)*
The GLOBAL UNITE Platform Shoulder System is intended for cemented or uncemented total or hemi-shoulder arthroplasty in treatment of the following:
• A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or
• rheumatoid arthritis
• Fracture 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
• Irreducible 3- and 4-part fractures of the proximal humerus
• Ununited humeral head fractures
• Avascular necrosis of the humeral head
• Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component)

Hemi-shoulder arthroplasty is also indicated for:
• Deformity and/or limited motion

The GLOBAL UNITE Reverse Fracture Epiphyseal Component, in conjunction with components from the existing DELTA XTEND™ Reverse Shoulder System and GLOBAL UNITE Platform Shoulder System, is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previously failed joint replacement with a gross rotator cuff deficiency. 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. It is intended for cemented or uncemented reverse shoulder arthroplasty in treatment of the following:
• Fracture 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
• Irreducible 3- and 4-part fractures of the proximal humerus
• Ununited humeral head fractures

The GLOBAL UNITE Reverse Fracture Epiphyseal Component is only intended for use in the treatment of proximal humeral fractures. Bone preparation instrumentation has not been validated to accommodate its use in a non-fracture press-fit application.

GLOBAL UNITE Humeral Stems, in conjunction with existing DELTA XTEND Epiphyseal Components, are indicated for use in reverse shoulder arthroplasty in treatment of a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the reverse implant(s), and a functional deltoid muscle is necessary to use the device.

When used in a total shoulder arthroplasty, the GLOBAL UNITE Implants are to be used with DePuy glenoid components. The glenoid components are for cemented use only. GLOBAL UNITE Humeral Implants are for cemented or uncemented use.

When used in a reverse shoulder arthroplasty, the GLOBAL UNITE and DELTA XTEND Humeral Implants are to be used with the HA-coated DELTA XTEND Metaglene Devices. The metaglene implants are intended for uncemented use only with additional screw fixation. The HA-coated DELTA XTEND Humeral Implants are intended for uncemented use

only. GLOBAL UNITE humeral implants are for cemented or uncemented use. The DELTA XTEND epiphyseal components are HA-coated and are intended for uncemented use.

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)

Submitter Information	
Name	DePuy Orthopaedics
Address	700 Orthopedic Drive Warsaw, IN 46582
Phone number	574-372-7276
Fax number	574- 371-4987
Establishment Registration Number	1818910
Name of contact person	Kellie Myers
Date prepared	11 January 2018
Name of device	
Trade or proprietary name	GLOBAL UNITE Platform Shoulder System
Common or usual name	Total, Hemi-, and Reverse Shoulder Arthoplasty Prosthesis
Classification name	Shoulder joint metal/polymer semi-constrained cemented prosthesis; Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3660; 21 CFR 888.3690
Product Code(s)	PHX; KWS; HSD
Legally marketed device(s) to which equivalence is claimed	***Zimmer Trabecular Metal*® Reverse Shoulder System**, K052906; ***Zimmer Trabecular Metal* Reverse Shoulder System**, Sizes 8mm and 10mm, K060704 **DePuy GLOBAL UNITE Shoulder System**, K101996 **DePuy GLOBAL UNITE Shoulder System**, K133834
Reason for 510(k) submission	This 510(k) submission is to add the GLOBAL UNITE Reverse Fracture Epiphysis to the currently cleared GLOBAL UNITE Platform Shoulder System, as well as to expand the currently cleared Indications for Use for the entire GLOBAL UNITE Platform Shoulder System.
Device description	The subject device expands the GLOBAL UNITE Platform Shoulder System (K101996, K133834) to include new porous-coated reverse fracture epiphyseal bodies made from titanium alloy that mate with existing GLOBAL UNITE (K101996) or DELTA XTEND (K071379) stems. In fracture cases with a grossly rotator cuff deficient glenohumeral joint with severe arthropathy where a surgeon deems reverse shoulder arthroplasty appropriate, the surgeon can use a GLOBAL UNITE (K101996) or DELTA XTEND (K071379) stem

	with the GLOBAL UNITE reverse fracture epiphysis and the DELTA XTEND metaglene and glenosphere (K062250).
Intended use of the device	Cemented or uncemented Total, Hemi-, or Reverse Shoulder Arthroplasty
Indications for use	The GLOBAL UNITE Platform Shoulder System is intended for cemented or uncemented total or hemi-shoulder arthroplasty in treatment of the following: • A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or • rheumatoid arthritis • Fracture 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 • Irreducible 3- and 4-part fractures of the proximal humerus • Ununited humeral head fractures • Avascular necrosis of the humeral head • Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component) Hemi-shoulder arthroplasty is also indicated for: • Deformity and/or limited motion The GLOBAL UNITE Reverse Fracture Epiphyseal Component, in conjunction with components from the existing DELTA XTEND™ Reverse Shoulder System and GLOBAL UNITE Platform Shoulder System, is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previously failed joint replacement with a gross rotator cuff deficiency. 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. It is intended for cemented or uncemented reverse shoulder arthroplasty in treatment of the following: • Fracture 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 • Irreducible 3- and 4-part fractures of the proximal humerus • Ununited humeral head fractures The GLOBAL UNITE Reverse Fracture Epiphyseal Component is only intended for use in the treatment of proximal humeral fractures. Bone

	preparation instrumentation has not been validated to accommodate its use in a non-fracture press-fit application. GLOBAL UNITE Humeral Stems, in conjunction with existing DELTA XTEND Epiphyseal Components, are indicated for use in reverse shoulder arthroplasty in treatment of a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the reverse implant(s), and a functional deltoid muscle is necessary to use the device. When used in a total shoulder arthroplasty, the GLOBAL UNITE Implants are to be used with DePuy glenoid components. The glenoid components are for cemented use only. GLOBAL UNITE Humeral Implants are for cemented or uncemented use. When used in a reverse shoulder arthroplasty, the GLOBAL UNITE and DELTA XTEND Humeral Implants are to be used with the HA-coated DELTA XTEND Metaglene Devices. The metaglene implants are intended for uncemented use only with additional screw fixation. The HA-coated DELTA XTEND Humeral Implants are intended for uncemented use only. GLOBAL UNITE humeral implants are for cemented or uncemented use. The DELTA XTEND epiphyseal components are HA-coated and are intended for uncemented use.
SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE	
The subject GLOBAL UNITE Platform Shoulder System is similar to the predicate Zimmer *Trabecular Metal* Reverse Shoulder System (K052906, K060704) and the predicate DePuy GLOBAL UNITE Shoulder System (K101996, 133834) in intended use, design, material, and fixation. The subject and predicate systems are intended for total, hemi-, or reverse shoulder arthroplasty; have modular anatomic/reverse convertibility; are made of titanium alloy; are intended for cemented or uncemented use; and include similar tissue reattachment options such as suture holes and suture collars. Differences include the type of modularity and fixation—the subject device and the predicate GLOBAL UNITE Shoulder System (K101996, 133834) are a modular stem-epiphysis design, while the predicate Zimmer *Trabecular Metal* Reverse Shoulder (K052906, K060704) is a monobloc stem with a dual taper adapter for the anatomic configuration. The subject device and the predicate GLOBAL UNITE Shoulder System (K101996, 133834) also use Porocoat® titanium porous coating for biological fixation, while the predicate Zimmer *Trabecular Metal* Reverse Shoulder (K052906, K060704) uses porous tantalum.	
PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE	
The following tests were performed (per FDA's *Guidance for Industry and FDA Staff – Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated*	

Uncemented Prosthesis) on the GLOBAL UNITE Shoulder System to demonstrate substantial equivalence of safety and efficacy with the predicate device:

- Fatigue Test for fracture stem with fracture epiphysis (at higher assembly torque)
- Fatigue Test for fracture stem with fracture epiphysis (at lower assembly torque)
- Fretting Corrosion Potential - Comparison to Existing Product
- Epiphysis Comparison
- 135˚ Neck Shaft Angle Verification
- 128˚ and 142˚ Neck Shaft Angle Verification
- Range of Motion Analysis
- Rationale for 155 Degree Neck-Shaft Angle
- Biocompatibility Study
- Mating Parts Analysis
- Effect of Screw Retention Insert of the Implant Packaging on Humeral Cup Seating
- Print Review of Product Marking
- Print Review of Suture Features
- Review of Label Content
- Print Review of Porocoat
- The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI AAMI ST-72:2011.

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

No clinical testing was conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject DePuy Synthes GLOBAL UNITE Shoulder System is substantially equivalent to the predicates *Zimmer Trabecular Metal* Reverse Shoulder System (K052906) and *Zimmer Trabecular Metal* Reverse Shoulder System, Sizes 8mm and 10mm (K060704).