DePuy Ireland UC
% Yayoi Fujimaki
Regulatory Project Manager
DePuy Mitek, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

September 15, 2021

Re: K212710
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: August 25, 2021
Received: August 26, 2021

Dear Yayoi Fujimaki:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212710

Device Name

GLOBAL UNITE™ Platform Shoulder System

Indications for Use *(Describe)*

Section 1: Applicable for the GLOBAL UNITE™ Platform Shoulder System with GLOBAL UNITE™ Standard or Revision/Long Humeral Stem Implants

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 developed 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 selected 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. Porous-coated epiphyses are intended for cemented or uncemented use. GLOBAL UNITE Humeral Implants are for cemented or uncemented use.

Section 2: Applicable for the GLOBAL UNITE™ Platform Shoulder System with GLOBAL UNITE™ Short Humeral Stem Implants

GLOBAL UNITE Short Humeral Stem Implants are for uncemented use only. The GLOBAL UNITE Platform Shoulder System with Short Humeral Stem is intended for 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

• 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

GLOBAL UNITE Short 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 selected 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.

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. Porous-coated epiphyses are intended for cemented or uncemented use. GLOBAL UNITE Short Humeral Stem Implants are for uncemented 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 - K212710

As required by 21 CFR 807.92 and 21 CFR 807.93

Submission Information		
Sponsor Name	DePuy Ireland UC	
Sponsor Address	Loughbeg, Ringaskiddy Co. Cork Ireland	
Sponsor Establishment Registration Number	3015516266	
510(k) Contact	Yayoi Fujimaki DePuy Mitek Regulatory Project Manager	Phone: 508.828.3541 Email: yfujima1@its.jnj.com
Date prepared	August 25, 2021	
Device Information		
Trade or proprietary name	GLOBAL UNITE™ Platform Shoulder System	
Common or usual name	Shoulder Prosthesis	
Classification name	Shoulder joint metal/polymer semi-constrained cemented prosthesis; Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis	
Class, regulation	Class II, 21CFR 888.3660, 21CFR 888.3690	
Product Code	PHX, KWS, HSD	
Classification panel	Orthopedics panel	
Legally marketed device(s) to which equivalence is claimed	Primary predicate: GLOBAL UNITE Platform Shoulder System short stem (DePuy Ireland: K202098) Additional predicate: GLOBAL UNITE Platform Shoulder System standard stem (DePuy Ireland: K101996, K170748)	
Device description	The Global Unite Platform Shoulder System is comprised of humeral stem, humeral head, suture collar and epiphyseal (anatomical or reverse) components. The subject Global Unite Short Stem is designed to conserve geometry and design features of the predicate Global Unite standard stem while eliminating the tapered distal stem body.	
Indications for use	<u>Section 1: Applicable for the GLOBAL UNITE Platform Shoulder System with GLOBAL UNITE Standard or Revision/Long Humeral Stem Implants</u> 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 developed 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 selected 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. Porous-coated epiphyses are intended for cemented or uncemented use. GLOBAL UNITE Humeral Implants are for cemented or uncemented use. <u>Section 2: Applicable for the GLOBAL UNITE Platform Shoulder System with GLOBAL UNITE Short Humeral Implants</u> GLOBAL UNITE Short Humeral Stem Implants are for uncemented use only. The GLOBAL UNITE Platform Shoulder System with Short Humeral Stem is intended for 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 • 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 GLOBAL UNITE Short 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 selected 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. 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. Porous-coated epiphyses are intended for cemented or uncemented use. GLOBAL UNITE Short Humeral Stem Implants are for uncemented use only.		
Summary of the Technological Characteristics of the Device Compared to the Predicate Devices			
Device	Subject Device: Global Unite Short Stem	Primary Predicate Device: Global Unite Short Stem	Additional Predicate Device: Global Unite Standard Stem
510(k)#	This submission	K202098 (DePuy)	K101996, K170748 (DePuy)
Intended Use	Total anatomical, hemi and total reverse arthroplasty	Total anatomical, hemi and total reverse arthroplasty	Total anatomical, hemi and total reverse arthroplasty
Cement	Cementless	Cementless	Cemented or cementless
Stem Material			
Body	Titanium alloy	Titanium alloy	Titanium alloy
Coating	POROCOAT® porous coating	POROCOAT® porous coating	POROCOAT® porous coating
Stem Design			
Diameter Size	8mm	10 to 16mm	6 to 16mm
Length	44mm	44 to 61mm	83 to 138mm
Others			
Sterilization	Gamma sterile, single use	Gamma sterile, single use	Sterile, single use
Testing Data			
Summary of non-clinical study	Biocompatibility evaluation per ISO10993-1. Dimensional and geometrical equivalency analysis, fatigue strength evaluation, tolerance analysis and torque testing are conducted. MRI compatibility evaluation is conducted for MRI labeling.		
Summary of animal study	Animal study was not necessary.		
Summary of clinical study	Clinical study was not necessary.		
Conclusion	The results of the non-clinical testing and evaluations have demonstrated that the subject device is as safe and effective as the predicate device and therefore, substantially equivalent to the predicate device.		