DePuy (Ireland)
% Megan Bernier
Regulatory Affairs Specialist
DePuy Orthopaedics, Inc.
325 Paramount Dr
Raynham, Massachusetts 02767

January 19, 2022

Re: K212683
Trade/Device Name: GLOBAL ICON Stemless Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC
Dated: December 14, 2021
Received: December 16, 2021

Dear Megan Bernier:

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 Jiping Chen, M.D., Ph.D., M.P.H.
Acting Division 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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K212683

Device Name
GLOBAL ICON Stemless Shoulder System

Indications for Use *(Describe)*

The Stemless Shoulder System is comprised of modular humeral fixation components and humeral heads to be used in total shoulder arthroplasty.

The Stemless Shoulder System is indicated for a severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis.

The Stemless humeral components are intended for press-fit fixation without the use of bone cement. The glenoid components are intended only for use with bone cement.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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	
Sponsor Name	DePuy Ireland UC
Sponsor Address	Loughbeg Ringaskiddy Co. Cork Ireland
Sponsor Establishment Registration Number	9616671
510(k) Contact	Megan Bernier Regulatory Affairs Specialist Telephone: (651-325-1178 Email: mbernie1@its.jnj.com
Date prepared	August 13th, 2021
Device Information	
Trade or proprietary name	GLOBAL ICON Stemless Shoulder System
Common or usual name	Total Shoulder Arthroplasty 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)	PKC
Legally marketed device(s) to which equivalence is claimed	Primary predicate: Zimmer Sidus Stem-Free Shoulder (K171858) Additional predicates: Tornier Simpliciti™ Shoulder System (K143552), Global Advantage Shoulder System (K011047, K992065, K984541). Reference devices: GLOBAL CAP HA Humeral Heads (K033516) and Pinnacle Duofix (K192919.
Reason for 510(k) submission	New device
Device description	The GLOBAL ICON Stemless Shoulder System includes cobalt-chromium alloy humeral heads that mate with titanium alloy anchor plates. The anchor plates include four grooved peripheral legs which are seated in the proximal humerus, and hydroxyapatite coating on all bone- contacting surfaces.

Intended use of the device	The GLOBAL ICON Stemless Shoulder System is comprised of modular humeral fixation components and humeral heads to be used in total shoulder arthroplasty.
Indications for use	The Stemless Shoulder System is comprised of modular humeral fixation components and humeral heads to be used in total shoulder arthroplasty. The Stemless Shoulder System is indicated for a severely painful and/ or disabled joint resulting from osteoarthritis or traumatic arthritis. The Stemless humeral components are intended for press-fit fixation without the use of bone cement. The glenoid components are intended only for use with bone cement.

	SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES			
Characteristic	**Subject Device: DePuy Synthes GLOBAL ICON Stemless Shoulder System**	**Primary Predicate Device: Zimmer Sidus Stem-Free Shoulder (K171858)**	**Predicate Device: Tornier Simpliciti Shoulder System (K143552)**	**Predicate Device: DePuy Synthes Global Advantage Shoulder System (K011047, K992065, K984541)**
Intended Use	Total Shoulder Arthroplasty	Total Shoulder Arthroplasty	Total Shoulder Arthroplasty	Total or Hemi Shoulder Arthroplasty
	Material			
Humeral Head	CoCrMo	CoCr alloy	CoCr alloy	CoCrMo
Humeral Fixation Component	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy
	Fixation			
Bone Cement	Uncemented	Uncemented	Uncemented	Cemented or uncemented
Fixation	Non-porous grit blast with additional plasma-sprayed HA coating	Non-porous grit blast with no additional surface coating	Porous-coating	Porous-coating
	Sterilization			
Sterile Method	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
Shelf-Life	10 years	5 years	5 years	10 years
	PERFORMANCE DATA			

	SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE
	The following tests were performed on the GLOBAL ICON Stemless Shoulder System to demonstrate substantial equivalence of safety and efficacy with the predicate devices: • Taper Analysis – Comparison to Existing Product • Micromotion and Subsidence Study • Surface Area Analysis • Fatigue and Head Extraction Study • Lever-Out Study • ROM Analysis • Wear Analysis • Humeral Head Analysis – Comparison to Existing Product • Bone-Conserving Analysis • MRI Analysis • Biocompatibility Study
	SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
	Included in this submission are interim 24-month data on 128 subjects. The primary endpoint in this study is a composite success endpoint at 24 months post-operative, where an individual study Subject is deemed to be a composite success if each of the criteria is met at the 24-month follow-up visit: • Radiographs indicate there is no continuous radiolucent line around the GLOBAL ICON Stemless Shoulder System humeral component. • The adjusted Constant-Murley score is greater than 85. • No GLOBAL ICON Stemless Shoulder System has been removed for any reason. • There were no device-related serious adverse events. The study data were successful in meeting the protocol-specified primary endpoint.

	Additionally: • There were no radiological signs of loosening or continuous radiolucent lines observed • There were no UADEs reported • There were no humeral components removed in 98.7% of Subjects • There were no device-related serious adverse events in 98.7% of Subjects • At 24-months the mean adjusted Constant-Murley Score improved by 60.4 points • At 24-months the adjusted Constant-Murley Score was greater than 85 in 85.1% of Subjects • Kaplan-Meier Survivorship estimate at 2.18 years is 98.72%
	The subject DePuy Synthes GLOBAL ICON Stemless Shoulder System is substantially equivalent to the primary predicate Zimmer Sidus Stem-Free Shoulder and additional predicates Tornier Simpliciti Shoulder System (K143552), and DePuy Synthes Global Advantage Shoulder System (K011047, K992065, K984541).