December 18, 2017

Zimmer GmbH
Dalene Binkley
Project Manager, Regulatory Affairs
1800 West Center Street
Warsaw, Indiana 46580

Re: K171858
Trade/Device Name: Sidus Stem-Free Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PKC
Dated: November 7, 2017
Received: November 8, 2017

Dear Dalene Binkley:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171858

Device Name
Sidus Stem-Free Shoulder

Indications for Use *(Describe)*
The Indications for Use of the Sidus Stem-Free Shoulder are:
- Osteoarthritis;
- Posttraumatic arthrosis;
- Focal avascular necrosis of the humeral head;
- Previous surgeries of the shoulder that do not compromise the fixation.

The Sidus Stem-Free Shoulder components (Anchors and Humeral Heads) are intended for cementless 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.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the *Sidus*™ Stem-Free Shoulder 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:

Zimmer GmbH
Sulzer Allee 8
CH-8404 Winterthur, Switzerland

Contact Person:

Dalene T. Binkley
Project Manager, Extremities Regulatory Affairs
Telephone: (574) 372-6789

Date:

December 15, 2017

Subject Device:

Trade Name: *Sidus* Stem-Free Shoulder
Common Name: Shoulder Prosthesis

Classification Name:
PKC – Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR § 888.3660)

Predicate Device(s):

K143552 (cleared 3/4/2015)	Primary Predicate: Simpliciti Shoulder System	Wright Medical (formerly Tornier)
K982981 (cleared 12/17/1998)	*Bigliani/Flatow* Shoulder Size 6mm x 60mm and Standard (concentric) Humeral Heads	Zimmer, Inc.

Purpose and Device Description:

The *Sidus* Stem-Free Shoulder is a modular humeral component (consisting of a humeral anchor and a head) designed to be used as a total- shoulder arthroplasty long-term implant. Both humeral anchor and humeral head components are available in multiple sizes.

The *Sidus* Stem-Free Shoulder replaces the proximal humeral bone, including the articulating surface, using an anatomical reconstruction surgical technique philosophy. The *Sidus* Stem-Free humeral anchor fixes within the proximal humeral bone via an uncemented interference press-fit. The *Sidus* Stem-Free humeral head mates to the *Sidus* Stem-Free humeral anchor via a Morse taper with the male taper on the humeral anchor and female taper on the humeral head.

Significant Physical and Performance Characteristics:
(1) Device Design: The *Sidus* Stem-Free Shoulder humeral anchor major design features include four fins, a baseplate and a male Morse taper. The *Sidus* Stem-Free Shoulder humeral head major design features include the articulation surface and a female Morse taper.
(2) Material Used: The *Sidus* Stem-Free Shoulder humeral anchor is made of a titanium alloy. The *Sidus* Stem-Free Shoulder humeral head is made of a cobalt chromium alloy.
(3) Physical Properties: The *Sidus* Stem-Free Shoulder humeral anchor is rough blasted on the four fins. The *Sidus* Stem-Free Shoulder humeral head is highly polished on the articulation surface.

Intended Use and Indications for Use:

The Indications for Use of the *Sidus* Stem-Free Shoulder are:

- Osteoarthritis;
- Posttraumatic arthrosis;
- Focal avascular necrosis of the humeral head;
- Previous surgeries of the shoulder that do not compromise the fixation.

The *Sidus* Stem-Free Shoulder components (Anchors and Humeral Heads) are intended for cementless use.

Summary of Technological Characteristics:

The *Sidus* Stem-Free Shoulder has the same intended use and fundamental scientific technology as its predicate devices. The technological characteristics (material, sizing, indications, coating, packaging, shelf life, and sterilization) of the *Sidus* Stem-Free Shoulder are substantially equivalent to the predicate device. The design differences have been demonstrated through clinical and non-clinical performance data do not raise new issues of safety or effectiveness.

Property or Characteristic	Proposed Device *Sidus* Stem-Free Shoulder	Primary Predicate Device Simpliciti Shoulder System (K143552)	Predicate Device *Bigliani/Flatow* Shoulder (K982981)
FDA Product Code(s)	PKC	PKC	HSD, KWS and KWT
Intended Use	Intended for Total Arthroplasty of the Shoulder	Intended for Total Arthroplasty of the Shoulder	Intended for Total or Hemi Arthroplasty of the Shoulder
Indications for Use	The Indications for Use of the *Sidus* Stem-Free Shoulder are: - Osteoarthritis; - Posttraumatic arthrosis; - Focal avascular necrosis of the humeral head; - Previous surgeries of the shoulder that do not compromise the fixation. The *Sidus* Stem-Free Shoulder components (Anchors and Humeral Heads) are intended for cementless use.	The Simpliciti Shoulder System is indicated for severely painful and/or disabled joint resulting from osteoarthritis and traumatic arthritis. The metaphyseal humeral stems are indicated for press-fit, un-cemented use. The glenoid components are indicated for cemented use only and are indicated only for use with bone cement. This device is for single use.	Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; ununited humeral head fractures of long duration; irreducible 3- and 4- part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights of 27 mm or greater may be used for difficult clinical management problems involving

			rotator cuff deficiency where arthrodesis or conventional nonconstrained arthroplasty is not acceptable.
Fixation Method	Uncemented (press fit)	Uncemented (press fit) - Porous	Cemented or Uncemented (press fit)
Sterilization for Anchor/Stem and Head	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Anchor/Stem Sizes	3 Sizes: Small (16mm), Medium (19mm) and Large (22mm)	3 Sizes: 18mm to 24mm	Diameter: 6mm to 16mm Length: 60mm to 200mm
Number of Fins	4 (fenestrated)	3 (full)	4 (full)
Anchor/Stem Coating	Rough blasted titanium	Sintered titanium bead coating	Rough blasted titanium
Head Diameter	38mm to 52mm	39mm to 56mm	40mm to 56mm
Head Thickness	13mm to 23mm	14mm to 23mm	15mm to 42mm
Material Substrate	Humeral Anchor: Titanium alloy Humeral Head: Cobalt Chromium alloy	Humeral Anchor: Titanium alloy Humeral Head: Cobalt Chromium alloy	Humeral Stem: Cobalt Chromium alloy Humeral Head: Cobalt Chromium alloy

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**

Non-clinical testing demonstrated that the *Sidus* Stem-Free Shoulder meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate devices in terms of safety and efficacy.

Non-Clinical Verification/Validation	Acceptance Criteria	Results

Literature review to ensure appropriate materials are used	Identify the most appropriate synthetic materials used to simulate the proximal humerus	Acceptable
Literature review of joint loading conditions	Identify the most appropriate loading conditions against which to evaluate the long-term performance of humeral implants	Acceptable
Analysis of acceptable implant geometry	Assess the geometry of the proximal humerus, fit of the implant and the cancellous bone material of the humerus.	Acceptable
Finite Element Analysis (FEA) – Stress Analysis	Use FEA to identify worst case conditions in-vivo.	Acceptable
Mechanical Testing - Fatigue	Verify sufficient fatigue strength	Acceptable
Finite Element Analysis (FEA) – Initial stability	Evaluate with FEA the initial fixation	Acceptable
Mechanical Testing - Primary Stability Testing	Determine the influence of bone quality and implant size on implant displacement	Acceptable
Mechanical Testing - Primary Stability with Cadaveric Testing	Verify primary stability in worst case physical testing in cadaveric bone	Acceptable
Magnetic Resonance Imaging (MRI) Analysis	Verify component can be used safely in a MRI environment	Acceptable

- **Clinical Tests:**

A Multicenter Investigational Device Exemption (IDE) Trial of the Sidus Stem-Free Shoulder Investigational was conducted in the United States and Canada to demonstrate the safety and effectiveness of the *Sidus* Stem-Free Shoulder. The results of this clinical study were compared to a Clinical Performance Goal using the stemmed *Bigliani/Flatow* prosthesis (*Sidus* IDE historical control). The Clinical Performance Goal for was established at 85.42% based on the historical performance of the *Bigliani/Flatow* Shoulder. The exact binomial confidence interval of the estimate is 72.24%. 93.93% (lower bound, upper bound).

To be considered a success, a *Sidus* subject must meet the following composite clinical success criteria at 2 years:

- ASES overall score improvement of at least 30 points from baseline.
- Radiographic success defined as:
  - No progressive radiolucencies of the humeral component > 2 mm, and
  - No progressive migration or subsidence of the humeral component ≥ 5 mm.
- No device-related serious adverse events (SAE).
- No reoperation or revision of the study implants.

93.0% of subjects included in the Sidus IDE analysis were considered a success based on the above criteria. In comparison, 85.4% of the Bigliani/Flatow historical control were considered a success based on the same criteria.

Study	Sample Size	N of Success	No of Failure	Percent of Success (PS)	95% Exact CI of PS
Sidus IDE	71	66	5	93.0%	(84.3%, 97.7%)
Historical Control	48	41	7	85.4%	(72.24%, 93.93)

In addition, 98.5% of Sidus IDE patients have over a 30 point improvement on the ASES score from preoperative. The study yielded excellent survivorship with 95.8% surviving. 98.5% of patients completing two year visits successfully passed the radiographic success criteria with no progressive radiolucencies of the humeral component >2 mm and no migration or subsidence of the humeral component. Three adverse events resulted in revision of the components and subsequent failure of the device.

In comparison, 91.7% of historical control patients have over a 30 point improvement on the ASES score from preoperative. The control yielded excellent survivorship with 97.9% surviving. 100% of patients exhibited radiographic success. 10.4% of patients experienced serious device related adverse events.

A total of 163 adverse events were reported in the Sidus IDE. 27 of those adverse events were determined to be definitely, possibly, or uncertain in their relation to the investigational device. Of these events, three revisions were reported. The first patient was revised by a non-study surgeon due to probable rotator cuff tear and possible loosening of the implants 7 months post-operatively. The non-study surgeon reported the subscapularis was possibly impinged between the head and anchor during the original implantation and was potentially the cause of the head not properly seating. The second revision occurred in a patient due to an acute subscapularis rupture 6 months post-operatively. The head and anchor were removed. The third revision included a patient who slipped on his garage floor 5 days post-operatively and fell with an outstretched arm resulting in a tear of the supraspinatous which was subsequently surgically repaired. The patient improved, but elected to proceed with shoulder revision surgery with a non-study surgeon. The operative report of the revising surgeon did not note any rotator cuff injury, infection or loose implants.

In comparison, the historical control study reported 5 serious adverse events probably related to the device. These events included glenoid loosening, rotator cuff tear, deep vein thrombosis leading to pulmonary embolism, superior migration of the humeral head leading to articulation with the acromion after lifting an 8 lb. weight and pain located at the anterior aspect of the shoulder requiring a second surgery.

A second Sidus study was conducted in Europe, *Sidus Stem-Free Shoulder: A Multicenter, Prospective, Non-Controlled Post-Market Clinical Follow-up Study (PMCF),* to further confirm performance of the device. When measuring PMCF subjects against the same Clinical Performance Goal, 88.4% of subjects were considered a success.

Sample	N of	N of	Percent	95%

Size	Success	Failure	of Success (PS)	Exact CI of PS
43	38	5	88.4%	(74.9%. 96.1%)

Thirteen adverse events were reported in the PMCF study. Adverse events were classified as not related, definitely related, possibly related, or unknown in their relation to the device. One event was categorized as an adverse device effect and included subluxation in the cranial direction due to insufficiency/rupture of the pectoralis major tendon. A second event occurred which included revision. This subject suffered a serious adverse event approximately 3.5 months after implantation which included a tear of the superior cuff and subsequent upward migration of the humeral head with pseudoparalysis. This resulted in device removal and subsequent revision of the study components.

Considering the performance data gathered during the Sidus IDE for the *Sidus* Stem-Free Shoulder, evidence suggests that it will perform equal or better than the currently marked *Bigliani/Flatow* stemmed shoulder for the intended use. This data was further supplemented by the evidence collected during the *Sidus* PMCF study.

Substantial Equivalence Conclusion

The *Sidus* Stem-Free Shoulder has the same intended use and the same fundamental scientific technology as the cleared Simpliciti Shoulder System and *Bigliani/Flatow* Shoulder System. Based on the clinical and non-clinical data presented for the subject and predicate devices, Zimmer GmbH concludes that subject device is substantially equivalent to the predicate device.