Zimmer GmbH
Anne-Kathrin Born
Regulatory Affairs Senior Specialist
Sulzerallee 8
Winterthur, 8404 Ch

August 6, 2019

Re: K191781
Trade/Device Name: Wagner SL Revision Stem Lateral and Wagner Cone Prosthesis System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH, KWZ, JDI
Dated: July 1, 2019
Received: July 2, 2019

Dear Anne-Kathrin Born:

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 Vesa Vuniqi
Acting 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)*

K191781

Device Name
Wagner Cone Prosthesis

Indications for Use *(Describe)*

• Noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
• Failed previous surgery where pain, deformity, or dysfunction persists.
• Optional use in revision: in some medical conditions (e.g., early revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.

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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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)*

K191781

Device Name
Wagner SL Revision Stem Lateral

Indications for Use *(Describe)*

• Revision of previously failed hip arthroplasty

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)

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Sponsor	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person	Anne-Kathrin Born Senior Specialist, Regulatory Affairs Telephone: +41 58 854 619 Fax: + 41 52 244 86 58
Date	June 26, 2019
Trade Name	Wagner Cone Prosthesis® System Wagner SL Revision Stem Lateral
Classification Product Code	LZO, LPH, KWZ, JDI
Device Classification Name	Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented Prosthesis, hip, constrained, cemented or uncemented, metal/polymer Prosthesis, hip, semi-constrained, metal/polymer, cemented
Regulation Number / Description	21 CFR § 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR § 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR § 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis 21 CFR § 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis
Predicate Device:	Wagner SL Revision Stem Lateral, manufactured by Zimmer GmbH, K043356, cleared 04/18/2005 Wagner SL Revision Stem Lateral, manufactured by Zimmer GmbH, K161192, cleared 07/08/2016 Wagner Cone Prosthesis System, manufactured by Zimmer GmbH, K113556, cleared 02/17/2012

Device Description:

The Wagner SL Revision Stem Lateral is a straight stem manufactured from forged titanium alloy and is available in four lengths. The neck design of the stem is provided with the standard 12/14 taper for connection with any Zimmer modular femoral head utilizing a 12/14 taper. The Wagner SL Revision Stem Lateral incorporates a circular stem cross-section and equally spaced conical anchorage ribs, which run nearly the full length of the stem.

The Wagner Cone Prosthesis stem is a straight, collarless stem system designed for uncemented fixation. The surface of the prosthesis is rough blasted, and it has a tapered shape with an angle of five degrees. The stem has eight longitudinal ribs, and it is available in two different CCD angles, 125° and 135°. The stems are available in twelve diameters, ranging from 13 to 24 mm.

Indications for Use:

Wagner Cone Prosthesis

- Noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Failed previous surgery where pain, deformity, or dysfunction persists.
- Optional use in revision: in some medical conditions (e.g., early revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.

Wagner SL Revision Stem Lateral and

- Revision of previously failed hip arthroplasty

Comparison to Predicate Device:

The intended use of the modified devices, as described in its labeling, has not changed as a result of the modifications proposed in the present submission. Zimmer GmbH proposes modification of the indications for use thereby limiting the indications within those of the previously cleared devices. Two indications for use are proposed to be removed for Wagner SL Revision stems and one indication for Wagner Cone Prosthesis is proposed to be reworded for more clarity. Modification of packaging configuration for the subject implant devices is proposed. The new packaging configuration and the methods to support the package integrity have been previously described in K182048 (Avenir Complete Hip System). The proposed changes do not alter the fundamental scientific technology shared by both the subject devices and predicate devices. Zimmer GmbH is furthermore seeking clearance for certain system-specific

	Class II instruments - these instruments that have previously considered Class I exempt and correction of classification to Class II is proposed within present submission.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: *Packaging configuration change:* Packaging performance testing was performed to verify that packaging configuration maintains integrity of the sterile barrier system up to the point of use and provides adequate protection to the product through the hazards of sterilization, handling, distribution and storage according to ISO 11607-1:2006 and ISO 11607-2:2006. Packaging Configuration testing was conducted by representative worst-case products. *Correction of instrument classification from Class I to Class II:* Amendment of Design Controls with verification of mechanical integrity and resistance. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.
Conclusion:	The subject devices have the same intended use and similar indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the same materials and processes as the predicate devices. Except for the modifications described in this submission the subject devices are identical to the predicate devices, and the performance data and analyses demonstrate that: • any differences do not raise new questions of safety and effectiveness as established with performance testing; and • the subject devices are at least as safe and effective as the legally marketed predicate devices.