DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 8, 2016

Zimmer GmbH
Ms. Anne-Kathrin Born
Regulatory Affairs Specialist
Sulzerallee 8/P.O. Box
CH 8404 Winterthur
Switzerland

Re: K161192
Trade/Device Name: Wagner SL Revision Stem Lateral, 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: June 8, 2016
Received: June 9, 2016

Dear Ms. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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)*
K161192

Device Name
Wagner SL Revision Stem Lateral
Wagner Cone Prosthesis® System

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.
• 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Anne-Kathrin Born Specialist, Regulatory Affairs Telephone: +41 58 85 48 619 Fax: + 41 52 244 86 58
Date:	April 26, 2016
Trade Name:	*Wagner Cone Prosthesis*® System *Wagner SL Revision Stem Lateral*
Classification Product Code / Device Classification Name:	**LZO** - Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented **LPH** - Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented **KWZ** - Prosthesis, hip, constrained, cemented or uncemented, metal/polymer **JDI** – 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 April 18, 2005

Wagner Cone Prosthesis® System, manufactured by Zimmer GmbH, K113556, cleared February 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.

No changes are being made to the *Wagner SL Revision Stem Lateral* and the *Wagner Cone Prosthesis* implants, but one change to the Awls is proposed in this submission:

- An additional energy type for driving the Wagner SL Awls and Wagner Cone Awls is introduced; from manually powered use only to manually **and** power driven use. While manually reaming is still possible the proposed modification enables the use of the awls connected to a powered device to ream the femoral medullary canal.

Intended Use:	No changes are made to the intended use of the *Wagner SL Revision Stem Lateral* and *Wagner Cone Prosthesis*® implants as a result of this modification. Indications for use include: - Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis; and inflammatory joint disease (IJD), e.g., rheumatoid arthritis. - Patients with failed previous surgery where pain, deformity, or dysfunction persists. - Revision of previously failed hip arthroplasty.
Comparison to Predicate Device:	The *Wagner SL Revision Lateral* and *Wagner Cone Prosthesis*® implants are not modified as compared to their predicates. Instead, an additional energy type for driving the Wagner SL Awls and Wagner Cone Awls is introduced; from manually powered use only to manually and power driven use. The *Wagner SL Revision Stem Lateral* and *Wagner Cone Prosthesis* ® implants are identical in intended use, materials, sterility, and performance characteristics to the predicate devices and remain unchanged.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The results of non-clinical performance testing and analyses demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Performance analyses included: 1. Usability Testing 2. Similar Device Analysis Clinical Performance and Conclusions: Clinical data and conclusions were deemed not needed to demonstrate substantial equivalence.