K113556 (pg. 1 of 2)

FEB 17 2012

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

Summary of Safety and Effectiveness

Sponsor:	Zimmer GmbH Sulzerallee 8 CH-8404 Winterthur, Switzerland
Contact Person:	Dan Williman Associate Project Manager, Regulatory Affairs Telephone: 573-371-8065 Fax: (574) 372-4605
Date:	January 17, 2012
Trade Name:	*Wagner Cone Prosthesis*® System
Product Code / Device:	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 Cone Prosthesis*, manufactured by Centerpulse Orthopaedics Inc., K032380, cleared September 22, 2003 *CLS™ Spotorno™* Femoral Stem, manufactured by Zimmer GmbH., K042249, cleared September 15, 2004
Device Description:	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.
Intended Use:	• 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.
Comparison to Predicate Device:	The *Wagner Cone Prosthesis* system is similar or identical in intended use, materials, sterility, and performance characteristics to the predicate devices.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The following tests have been completed in support of the changes to the *Wagner Cone Prosthesis* system: Stem and Neck Fatigue Testing, Biocompatibility Testing, and Burst Strength Testing of Ceramic Femoral Heads Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 17 2012

Zimmer, Inc.
% Mr. Dan Williman
Associate Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K113556
Trade/Device Name: *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: January 17, 2012
Received: January 19, 2012

Dear Mr. Williman:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113556

Device Name:

Wagner Cone Prosthesis® System

Indications for Use:

- 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.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113556