K043356 (pg 1 of 2)

APR 1 8 2005

510(k) SUMMARY

SPONSOR NAME: Zimmer Austin, Inc.
9900 Spectrum Drive
Austin, TX 78717

MANUFACTURER: Zimmer GmbH
Sulzer Allee 8
Winterthur, 8404
Switzerland

CONTACT: Audrey Swearingen
Phone: (512) 432-9255
E-Mail: audrey.swearingen@zimmer.com

TRADE NAME: Wagner SL Revision Stem Lateral

COMMON NAME: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

CLASSIFICATION: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses (Product Code 87 LZO) are Class II per 21 CFR §888.3353, reviewed by the Orthopedic Devices panel.

PREDICATE DEVICE: Wagner SL Revision Stem (K953689)

DEVICE DESCRIPTION:
Both the existing Wagner SL Revision Stem and the proposed Wagner SL Revision Stem Lateral are manufactured from forged titanium alloy and are available in three lengths (225mm, 265mm and 305mm). The neck design of both stems 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, as do the ribs of the previously cleared Wagner SL Revision Stem. The surface of both stems is rough-blasted.

To achieve the lateralization of the modified device, the CCD (i.e., neck) angle was reduced to 135° and the neck was lengthened. To compensate for the increased bending moments and lateral stresses, which result from the increased offset, the rib structure was rotated by 22.5° so that the greatest bending moment would not be concentrated on a rib; and the ribs were widened, which led to an increase in the stem strength.

In addition, a threaded coupling was added to the proximal portion of the stem for use with the new impactor/extractor instrument, the cone was shortened and the stem neck thinned down to increase the range of motion, and two small holes were added to the proximal portion of the stem for securing non-metallic suture material.

INTENDED USE:

The Wagner SL Revision Stem Lateral is intended for prosthetic replacement of the proximal portion of the femur during total hip arthroplasty. It is intended for press-fit application. Specific diagnostic indications 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.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The device, as modified, is substantially equivalent in terms of fundamental design, materials, manufacturing, indications for use and intended use to the previously cleared, currently marketed Wagner SL Revision Stem.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2005

Ms. Audry Swearingen
Regulatory Affairs Manager
Zimmer Austin, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K043356
Trade/Device Name: Wagner SL Revision Stem Lateral
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or Nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: March 17, 2005
Received: March 21, 2005

Dear Ms. Swearingen:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043356

Device Name: Wagner SL Revision Stem Lateral

Indications for Use:

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- Revision of previously failed hip arthroplasty.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043356

(Posted November 13, 2003)