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SEP 15 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Zimmer Austin, Inc.
9900 Spectrum Drive
Austin, TX 78717
(512) 432-9255

Manufacturer: Zimmer GmbH
Sulzer Allee 8
Winterthur, 8404
Switzerland

Date: August 16, 2004

Contact Person: Audrey Swearingen
Manager, Regulatory Affairs

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21CFR 888.3353

Common/Usual Name: Femoral Stem

Trade/Proprietary: CLS™ Spotorno™ Stem

Product Description:

The CLS™ Spotorno™ Femoral Stem is intended for use as a prosthetic replacement of the proximal portion of the femur during total hip arthroplasty. It is indicated for cementless use in total hip replacement in treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis and conditions of inflammatory degenerative joint disease (IJD), e.g. rheumatoid arthritis;
- those patients with failed previous surgery where pain, deformity, or dysfunction persists;
- revision of previously failed hip arthroplasty

This Special 510(k) incorporates the following changes as compared to the original device configuration: 1) addition of the CLS 125° stem, with an increased offset; and 2) incorporation of a slim neck and short taper. Below the resection line, the design of the modified stem remains the same as the legally marketed device.

Substantial Equivalence:

The modified CLS™ Spotorno™ Stem is substantially equivalent in terms of fundamental design, materials, manufacturing, indications for use and intended use to the previously cleared, currently marketed CLS™ Stems.

Verification activities included fatigue testing of the CLS 125° to ensure that the modified design is safe and effective. All test samples met the acceptance criteria, thus indicating that the device, as modified, will survive physiological loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2004

Ms. Audrey Swearingen
Manager, Regulatory Affairs
Zimmer Austin, Inc.
9900 Spectrum Drive
Austin, TX 78717

Re: K042249
Trade/Device Name: CLS™ Spotorno™ Femoral Stem
Regulatory 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: August 18, 2004
Received: August 19, 2004

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K042249

Device Name: CLS™ Spotorno™ Stem

Indications for Use:

The CLS™ Spotorno™ Femoral Stem is intended for cementless use in total hip replacement in treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis and conditions of inflammatory degenerative joint disease (IJD), e.g. rheumatoid arthritis;
- those patients with failed previous surgery where pain, deformity, or dysfunction persists;
- 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)

Miriam C. Provost

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

510(k) Number K042249

(Posted November 13, 2003)