JAN - 6 1998

510(k) SUMMARY K973837

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the use of zirconia ceramic heads with the femoral stems listed below.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	September 30, 1997
Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR 888.3353
Common/Usual Name:	Total Hip Prosthesis, Semi-constrained
Trade/Proprietary Name:	Zirconia Ceramic Total Head (12/14) for use with the CLS Stem, Wagner Revision Stem, and, AlloClassic Zweymuller Stem SL

SPECIFIC DIAGNOSTIC INDICATIONS

The CLS, Wagner Revision and AlloClassic Zweymuller femoral stems will be used in conjunction with the Zirconia Ceramic Total Head. This stem/head combination is intended for prosthetic replacement of the proximal portion of the femur during total hip arthroplasty in which the ball head articulates with a polyethylene acetabular component. Specific diagnostic indications include:

- Patient conditions of inflammatory degenerative joint disease (e.g., rheumatoid arthritis) and noninflammatory degenerative joint disease (e.g., osteoarthritis, avascular necrosis);
- Those patients with failed previous surgery where pain, deformity, or dysfunction persist; and,
- Revision of previously failed hip arthroplasty.

The CLS Stem, Wagner Revision Stem and AlloClassic Zweymuller Stem, are intended for use with or without bone cement.

PRODUCT DESCRIPTION

The CLS Stem, Wagner Revision Stem and AlloClassic Zweymuller Stem are all designed for use with ceramic heads. These stems are manufactured from Ti-6Al-7Nb alloy and have the same proximal taper which is machined per the specifications of the 12/14 Sulzer taper.

The Zirconia Ceramic Total Head is a spherical head with a 12/14 taper, making it compatible with the above stems. The heads are available in 28mm and 32mm diameters and three neck lengths; short, medium and long.

Static compression testing demonstrated that the burst strength of the zirconia heads exceeds FDA requirements.

SUBSTANTIAL EQUIVALENCE

The CLS Stem, the Wagner Revision Stem, and the AlloClassic Zweymuller Stem when used with the Zirconia Ceramic Total Head are substantially equivalent to the APR and Natural Hip Systems (Sulzer Orthopedics Inc.).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 1998

Ms. Shavawn Evans Parduhn
Regulatory Affairs Specialist
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Ausitn, Texas 78717

Re: K973837
CLS Stem, Wagner Revision Stem, AlloClassic Zweymuller Stem, SL for use with Zirconia Ceramic Heads
Regulatory Class: II
Product Code: LZO
Dated: October 7, 1997
Received: October 8, 1997

Dear Ms. Parduhn

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation that the package insert must reflect that the Metoxit Zirconia Ceramic Femoral Heads are to be used only with Ti-6Al-7Nb hip stems with the Sulzer 12/14 (5°38' cone angle) Morse taper trunnions.

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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug

Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: CLS Stem, Wagner Revision Stem and AlloClassic Zweymuller Stem for Use With Zirconia Ceramic Total Heads

Indications For Use:

The CLS, Wagner Revision and AlloClassic Zweymuller femoral stems will be used in conjunction with the Zirconia Ceramic Total Head. This stem/head combination is intended for prosthetic replacement of the proximal portion of the femur during total hip arthroplasty in which the ball head articulates with a polyethylene acetabular component. Specific diagnostic indications include:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ **OR** **Over-The-Counter Use** _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973837