K981211

MAY 22 1998

510(k) SUMMARY

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:	April 1, 1998
Contact Person:	Mitchell A. Dhority Manager, Regulatory Affairs
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis, 21 CFR 888.3358
Common/Usual Name:	Total Hip Prosthesis, Semi-constrained
Trade/Proprietary Name:	APR-T® Revision Hip Stem

SPECIFIC DIAGNOSTIC INDICATIONS

The APR-T Revision Hip Stem is intended for prosthetic replacement of the proximal portion of the femur during hip arthroplasty. This hip stem can be used for total hip replacements (i.e., replacements where both the femur and acetabulum are replaced) or for hemi-arthroplasties where the hip stem-head assembly articulates directly with well-preserved articular cartilage. 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 APR-T Revision Hip Stem is intended for use with or without bone cement.

PRODUCT DESCRIPTION

The APR-T Revision Hip Stem is part of a family of femoral replacement components which are used during primary and revision hip arthroplasties. Its proximal design features an asymmetric wedge and circumferential CSTi ™ porous coating. In addition, a porous-coated medial collar helps achieve improved proximal fixation.

The stem's anatomic design follows the natural curve of the diaphyseal canal for better fit, and features a coronal slot at the distal end to reduce stiffness in the larger sizes.

SUBSTANTIAL EQUIVALENCE

This 510(k) is being submitted in response to an update of the design such that certain features are uniform across the entire APR stem line. The characteristics of the APR-T Revision Stem, either alone or in combination, are substantially equivalent to the following legally marketed predicate Sulzer Orthopedics and/or competitive devices in terms of intended use, materials and design characteristics: the APR® Collared Revision Stem (Sulzer Orthopedics Inc.), the APR® Porous Hip Stem (Sulzer Orthopedics Inc.), the BIAS™ Total Hip Prosthesis (Zimmer, Inc.), the PCA ™ Long Stem (Howmedica, a Division of Pfizer Hospital Products Group, Inc.), and the Natural-Hip™ Porous Stem (Sulzer Orthopedics Inc.).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1998

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

Re: K981211
Trade Name: APR-T® Revision Stem
Regulatory Class: II
Product Codes: LPH and JDI
Dated: April 1, 1998
Received: April 2, 1998

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. 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. 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 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): K981211

Device Name: **APR-T Revision Hip Stem**

Indications For Use:

The APR-T Revision Hip Stem is intended for prosthetic replacement of the proximal portion of the femur during hip arthroplasty. This hip stem can be used for total hip replacements (i.e., replacements where both the femur and acetabulum are replaced) or for hemi-arthroplasties where the hip stem-head assembly articulates directly with well-preserved articular cartilage. For this indication, the stem must be paired with one of the following Sulzer Orthopedics endoprosthesis:

- the Unipolar with 12/14 Taper, cleared for use via 510(k)s K833403 and K934159, or
- the Bipolar component which was cleared for use via 510(k)s K833404 and K873815 and is indicated for use with a CoCr modular femoral head.

Specific diagnostic indications include:

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

The APR-T Revision Hip Stem is intended for use with or without bone cement.

(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 General Restorative Devices
510(k) Number K981211

Prescription Use Yes OR Over-The-Counter Use No

(Optional Format 1-2-96)