

K97 3124

NOV - 3 1997

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 510(k) Summary for the APR Porous HA Hip Stem.

Submitter: Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717
(512) 432-9900

Date: August 19, 1997

Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR 888.3358.

Common/Usual Name: Biologically fixed total hip prosthesis, semi-constrained

Trade/Proprietary Name: APR Porous HA Hip Stem

PRODUCT DESCRIPTION

The APR Porous HA femoral stem is anatomically designed with right and left components. These stems are available in three proximal body styles to optimize fit of the hip stem in the femoral canal: a standard body, a large body in which the proximal anterior dimension has been widened slightly to maximize filling of the proximal femur, and an oversized for the patient exhibiting the endosteal canal shape (sometimes referred to as Type A) in which the diaphysis is disproportionately smaller than the metaphysis. The larger sizes of the stems are stems feature distal hollowing for increased stem flexibility.

The stems are manufactured from wrought Ti-6Al-4V (ASTM F-136). The stems are fabricated with a neck and stem designed to match the natural shape and curve of the femur. Ceramic hydroxylapatite (HA) coated Cancellous-Structured Titanium (CSTi) is located on the inferior side of the collar as well as the proximal femoral body. A morse-type taper on the proximal aspect of the stem permits attachment of one of a variety of femoral heads.

This device is intended for use with the following previously cleared devices:

- IOI metallic femoral bearing heads
- IOI Biolox Bearing Heads
- Zirconia Bearing Heads
- IOI acetabular components

SPECIFIC DIAGNOSTIC INDICATIONS

The APR Porous HA Hip Stem is intended to replace the anatomy of the femur in cases of total hip or hemi-hip replacement. The general indications associated with the use of the APR Porous HA Hip Stem in total hip arthroplasty include:

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

Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient, and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

The APR Porous HA Hip Stem is intended only for use without bone cement in the United States. This device is intended for single use only.

SUBSTANTIAL EQUIVALENCE

The APR Porous HA Hip Stem is substantially equivalent to the Natural-Hip HA Stem (Sulzer Orthopedics Inc.) and the APR Universal Hip Stem with Calcitite®-Coated CSTi (Sulzer Orthopedics Inc.).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lori Kleinschrodt Holder, RAC
Regulatory Affairs Specialist
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717

NOV - 3 1997

Re: K973124
APR Porous HA Hip Stem
Regulatory Class: II
Product Codes: LPH and MEH
Dated: August 19, 1997
Received: August 20, 1997

Dear Ms. Holder:

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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for enhanced clinical or radiographic performance, enhanced biological fixation and/or long-term stable fixation. The data presented support equivalence with no additional claims over a conventional porous-coated uncemented hip prosthesis (i.e., biological fixation, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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 requirements, 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. 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.

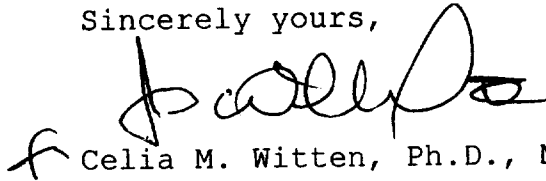
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

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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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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): K973124

Device Name: APR Porous HA System

Indications For Use:

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

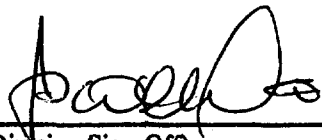
The APR Porous HA System is intended only for use without bone cement.

(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 K973124