K973675

510(k) SUMMARY DEC 19 1997

In accordance with the Food and Drug Administration Interim 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 Sulzer Orthopedics Inc. Natural-Hip Porous Stem with Offset.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, TX 78717 (512)432-9900
Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	21 CFR 888.3358 - Hip joint metal/polymer/metal porous uncemented prosthesis
Common/Usual Name:	Femoral stem component for hip replacement
Trade/Proprietary Name:	Natural-Hip Porous Stem with Offset

PRODUCT DESCRIPTION:

The Natural-Hip Porous Stem with Offset is a straight stem available in both a collared and collarless design. The design of the neck/taper region provides 6-7mm of offset to allow the surgeon to more closely approximate the normal femoral head center in cases where varus deformity may be present. The component is manufactured from forged titanium alloy (Ti-6AL-4V, ASTM F620). The proximal surface of the stem employs circumferential CSTi porous coating to provide biological fixation which reduces tracks of debris, thereby potentially inhibiting osteolysis. The collared stem employs CSTi porous coating on the inferior surface of the collar to prevent calcar resorption by providing biological fixation and load transfer in cementless applications. The proximal anterior surface of the stem employs anterior angulation or build-up to match the anatomic angulation of a natural femur. The superior portion has a built-in anteversion of nine degrees (9°) to match the anatomic anteversion of the femur. Due to this feature, separate left and right components are offered. The distal portion of the stem employs ribs and flutes on the anterior and posterior sides to enhance cortical contact, thereby providing rotational stability to the stem. In addition, the distal portion of the stem has a flared coronal slot which reduces stem stiffness. The slot provides optimal distal fill of the femoral canal for additional rotational stability. A Sulzer 12/14 configured neck trunnion allows for attachment to a metallic, Biolox, or Zirconia femoral head having a Sulzer 12/14 configured bore

SPECIFIC DIAGNOSTIC INDICATIONS:

The Natural-Hip Porous Stem with Offset is intended for use in cases of hemi- or total hip replacement for treatment of the following:

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 hip arthroplasty.

SUBSTANTIAL EQUIVALENCE:

Substantial equivalence determination is based on comparison of the Natural-Hip Porous Stem with Offset to the following legally marketed predicate competitive devices:

- Sulzer Orthopedics Natural-Hip Porous Stem
- Howmedica Precision Strata Offset Stem
- Johnson & Johnson PFC Offset Stem
- DePuy Endurance Offset Stem
- DePuy Stability Offset Stem
- Osteonics Omnifit Enhanced Offset Stem

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

Ms. Jacquelyn Hughes
Manager, Regulatory Affairs
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K973675
Trade Name: Sulzer Orthopedics Natural-Hip Porous Stem with Offset
Regulatory Class: II
Product Code: LPH
Dated: September 25, 1997
Received: September 26, 1997

Dear Ms. Hughes:

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,

for 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): K973675

Device Name: Sulzer Orthopedics Natural-Hip Porous Stem with Offset

Indications for Use:

The Natural-Hip Porous Stem with Offset is intended for use in cases of hemi- or total hip replacement for treatment of the following:

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 hip arthroplasty.

(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 K973675

Prescription Use X **OR** **Over-the Counter Use** ____

(Optional Format 1-2-96)