

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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 Precedent Revision Hip System without HA.

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

Date: July 14, 1997

Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

Classification Name: Hip Joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis - 21CFR 888.3353 (87LZO).

Common/Usual Name: Femoral hip prosthesis

Trade/Proprietary Name: Precedent Revision Hip System

PRODUCT DESCRIPTION

The Precedent Revision Hip System is manufactured from either wrought or forged titanium alloy. The Precedent Revision Hip System features a threaded Sulzer 12/14 configured neck trunnion for attachment to Sulzer Orthopedics' currently marketed femoral heads, including BioloX and Zirconia heads, employing a Sulzer 12/14 configured bore. The Precedent Revision Hip System is available in both a collared and collarless design to address surgeon preference. The entire length of the Precedent Revision Hip System, except the neck region and the distal tip, is roughened via the process of grit blasting. The distal portion of the Precedent Revision Hip System employs flutes which cut into the distal cortices of the prepared femoral canal, thereby providing rotational stability to the hip stem. In addition, the Precedent Revision Hip System employs a coronal slot which potentially reduces bending stiffness of the distal stem and thigh pain. The distal tip of the Precedent Revision Hip System is polished to a machined finish to provide ease of insertion during surgery.

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

- Sulzer Orthopedics metallic femoral bearing heads
- Sulzer Orthopedics BioloX Bearing Heads
- Sulzer Orthopedics Zirconia Bearing Heads
- Sulzer Orthopedics bipolar components
- Sulzer Orthopedics unipolar components
- Sulzer Orthopedics acetabular components

SPECIFIC DIAGNOSTIC INDICATIONS

Precedent Revision Hip System is primarily intended to address femoral bone deficiencies associated with failure of primary total or hemi-hip arthroplasties. In addition, the Precedent Revision Hip System, like the predicate competitive hip stems, is intended for cementless application.

The general indications associated with the use of the Precedent Revision Hip System 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 Precedent Revision Hip System is intended only for use without bone cement in the United States. This device is intended for single use only.

SUBSTANTIAL EQUIVALENCE

The Precedent Revision Hip System is substantially equivalent to the following legally marketed predicate competitive devices:

- Sentry Femoral Component: Howmedica Inc.
- S-ROM® Femoral Prosthesis: Joint Medical Product Corporation.
- Stability Hip Stem: Depuy Inc.
- Wagner Revision Stem: Protek Inc.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT - 1 1997

Re: K972637
Trade Name: Precedent Revision Hip System
(Grit Blasted)
Regulatory Class: II
Product Code: LZO
Dated: July 14, 1997
Received: July 15, 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). 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.

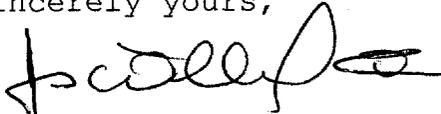
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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): K972637

Device Name: Precedent Revision Hip System without HA

Indications For Use:

The general indications associated with the use of the Precedent Revision Hip system without HA in total hip arthroplasty include:

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 Precedent Revision Hip System without HA 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)



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K972637

Prescription Use X

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)