510(k) SUMMARY

K022985
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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 Sulzer Orthopedics Ascendant Acetabular Shell System.

DEC 0 5 2002

Manufacturer:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	October 21, 2002
Contact Person:	Mitchell A. Dhority Regulatory Affairs Dept.
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21CFR 888.3353 (LZO) Hip joint metal/metal semiconstrained, with an uncemented acetabular component, prosthesis, 21CFR 888.3330 (KWA) Hip joint metal/polymer semi-constrained cemented prosthesis, 21CFR 888.3350 (JDI) Hip joint metal/polymer semi-constrained uncemented prosthesis (LWJ)
Common/Usual Name:	Nonporous, press-fit, acetabular shell system
Trade/Proprietary Name:	Sulzer Orthopedics Ascendant™ Acetabular System

PRODUCT DESCRIPTION

The Ascendant Acetabular System consists of two modular shell options which mate with currently marketed insert components for replacement of the acetabulum during total hip arthroplasty. They are designed to provide congruency with the ability to effectively seal the acetabulum, and may be implanted with or without bone cement. Press-fit fixation (e.g. cementless) to the bone is achieved by an oversized shell with a grit blasted, Chemtex® (chemically textured process) surface.

1. Common Features

   The following design features are common to the two metallic shells of the Ascendant Acetabular System family:

   - Substrate Material – The Ascendant shells are manufactured from titanium alloy (Ti-6Al-4V, ASTM F136).

- Surface – The surface of the Ascendant shells are manufactured with a grit blasted, Chemtex® (chemically textured process) surface.
- Shell/Insert Locking Mechanism – The two shells of the Ascendant System share the same internal locking mechanism as the previously cleared Converge Cluster Hole and Multi-Hole Acetabular Shells. Moreover, they can be used with the currently marketed Sulzer Orthopedics Epsilon (formerly Inter-Op) Acetabular Inserts (standard polyethylene (Sulene), Durasul® and Metasul®). Additionally, the inside diameter of the shell also provides maximum congruency and optimizes load transfer from the polyethylene insert to the metallic shell.
- Threaded Dome Hole/Dome Hole Plug – The two shells of the Ascendant System feature the same threaded dome hole as the previously cleared Converge Acetabular Shells. During implantation of the shell, an impactor/alignment instrument with mating threads is inserted into the dome hole to place the shell into the acetabulum. Once the shell has been inserted and the impactor/alignment tool is removed, the dome hole provides visual access to the acetabulum so that the surgeon can ensure complete seating of the device. Once adequate seating of the device into the acetabulum has been assured, the threaded titanium dome hole plug (ASTM F67) can be screwed into place to prevent unwanted material migration through the dome hole. Once in place, the plug is recessed within the dome hole and does not protrude beyond the outer diameter of the shell.

2. Shell Options

The following is a description of product-specific features for each of the shell components of the Ascendant product family:

a) Ascendant Cluster-Hole Shell with Sealed Screw Holes

The Ascendant Cluster-Hole shell is a hemispherically shaped acetabular shell that features screw holes sealed with threaded plugs. The plugs may be removed during surgery, if desired, to allow for supplemental fixation with bone screws.

The cluster-hole shell features two to three superior holes (depending on shell size) in order to increase fixation options. The shells are offered in 17 sizes, reflective of the outer shell diameter, ranging from 39mm to 71mm, in 2mm increments.

When left in place, the screw hole plugs limit the potential for fibrous tissue growth (for cementless application) or cement extrusion (in cemented application) into the shell. The plugs also act to restrict debris from migrating through the acetabular shell holes into the acetabulum.

If the surgeon opts to provide additional fixation of the device, the shell's screw holes will accommodate bone screw attachment to the ilium. Removal of the sintered plugs is accomplished with the use of a specially designed removal tool.

b) Ascendant Multi-Hole Shell with Sealable Screw Holes

The Ascendant Multi-Hole Shell with Sealable Screw Holes is a hemispherical shell designed to expand the surgeon's options for treatment of scenarios where acetabular bone stock is deficient (e.g., revision cases).

The Multi-Hole Shell features five to nine screw holes (depending on shell size), to allow for screw placement into the ilium, ischium, and pubis. Three to five of the screw holes are located at the ilium, which normally provides more bone stock for attachment. There are one to two screw holes each in the ischium and pubis regions.

Screw holes that are not used in attaching the shell to the acetabulum can be plugged in order to limit the potential for fibrous tissue growth into the shell (for cementless application) or cement extrusion into the shell. A secondary benefit of the plugs in both applications is their ability to restrict debris from migrating through the acetabular shell holes into the acetabulum. The plugs may be manufactured from Ti-6Al-4V (ASTM F136).

The Ascendant Multi-Hole Shell with Sealable Screw Holes is available in outer diameters ranging from 43mm to 81mm, in 2mm increments.

SPECIFIC DIAGNOSTIC INDICATIONS

Components of the Ascendant Acetabular System are intended for use in total hip arthroplasty for treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD); e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- revision of a previously failed arthroplasty.

SUBSTANTIAL EQUIVALENCE

The Ascendant Acetabular Shell System is similar to the following commercially available devices in terms of materials, general design features, and intended uses:

- Sulzer Orthopedics Inter-Op Acetabular System
- Sulzer Orthopedics Converge Acetabular System
- Stryker/Osteonics/Howmedica System 12 Acetabular System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2002

Mr. Mitchell Dhority
Manager, Regulatory Affairs
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K022985
Trade Name: Sulzer Orthopedics Ascendant™ Acetabular System
Regulation Number: 888.3353; 888.3350; 888.3330
Regulation Names: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented posthesis; Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis; and Hip joint metal/polymer semi-constrained uncemented prosthesis
Regulatory Class: Class II and Class III
Product Codes: LZO, JDI, KWA, LWJ
Dated: October 23, 2002
Received: October 24, 2002

Dear Mr. Dhority:

We have reviewed your Section 510(k) premarket 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 legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

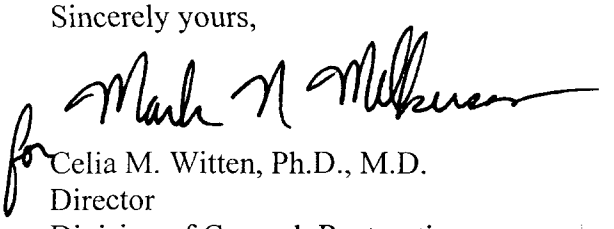
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



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

Enclosure

510(k) Number (if known): K022985

Device Name: Ascendant Acetabular System

Indications for Use:

Components of the Ascendant Acetabular System are intended for use in total hip arthroplasty for treatment of the following:

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022985