

SEP 19 1997

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 21CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Inter-Op™ HA Porous Acetabular System.

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| Submitter: | Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9687 |
| Date: | May 19, 1997 |
| Contact Person: | Jacquelyn Hughes Manager, Regulatory Affairs |
| Classification Name: | Hip Joint Metal/Polymer/Metal Semi-constrained Porous-coated Uncemented Prosthesis, 21CFR 888.3358 |
| Common/Usual Name: | Biologically fixed metal-backed acetabular component |
| Trade/Proprietary Name: | Inter-Op™ HA Porous Acetabular System |

PRODUCT DESCRIPTION

The Inter-Op™ HA Porous Acetabular System consists of a Ti-6Al-4V alloy (ASTM F136) shell which utilizes a polyethylene snap-in liner. Hydroxylapatite (HA) coated Cancellous Structured Titanium™ (CSTi™) porous coating provides biological fixation in a cementless application. The shells are available in a variety of sizes and designs to address different clinical situations in both primary and revision arthroplasties. Inter-Op HA Porous Acetabular Components are recommended for use with all Sulzer Orthopedics total hip replacement devices.

The system includes two primary designs: (1) a hemispherical shell with an offset outer radius in the rim region, which permits the loads to be transmitted to the periphery of the outer surface; and (2) a hemispherical shell with two plugged screwholes. The plugs may be removed intraoperatively for additional screw fixation, if desired. A dome hole plug is also provided.

Two multi-holed shells designed for screw application are provided for those clinical situations in which deficient bone stock exists in the acetabulum. Those screwholes that are not utilized may be plugged after implantation. This shell is available in two designs: (1) a standard hemispherical cup, and (2) a protrusio cup which adds 10mm of thickness of the medial wall over a standard hemispherical cup to address protrusio deficiencies in the acetabulum. A dome hole plug is also provided.

All the shell designs share identical internal geometry and locking mechanism thereby accepting any of the acetabular liners designed for this system. The acetabular liner is manufactured from Ultra-High Molecular Weight Polyethylene, or UHMWPE (ASTM F648) and is offered in various configurations in order to address different clinical situations. The liners are also available in a variety of sizes to accommodate available femoral head components.

The integrity of the locking mechanism Inter-Op HA Porous Acetabular Component was investigated by examining the attachment strength between the acetabular shell and acetabular insert. The strength of the locking mechanism compares favorably to other currently marketed devices.

DIAGNOSTIC INDICATIONS

Components of the Inter-Op HA Porous Acetabular System are intended to replace the acetabulum during total hip arthroplasty. The four metallic shell styles are porous coated and used in conjunction with a snap-in polyethylene liner. The acetabular components of this system are intended to achieve biological fixation to bone without the use of bone cement.

While three of the shell styles are hemispherical, the Protrusio HA Porous Shell is designed to compensate for protrusio defects where there has been thinning of the medial and superior walls of the acetabulum. The inner diameter is hemispherical while the outer shell has a 10mm build up, thus maintaining the anatomical hip center and avoiding the medialization of the femoral component.

General diagnostic indications for use of components of the Inter-Op HA Porous Acetabular System include:

- revision of a previously implanted acetabular prosthesis;
- patient conditions of noninflammatory degenerative joint disease; e.g., avascular necrosis, osteoarthritis, or arthritis secondary to a variety of diseases and anomalies; and,
- inflammatory joint disease; e.g., rheumatoid arthritis.

SUBSTANTIAL EQUIVALENCE

The Inter-Op HA Porous Acetabular System is substantially equivalent to the predicate components of the Inter-Op Porous Acetabular System (Sulzer Orthopedics Inc.) and to the APR HA Porous Hip System (Sulzer Orthopedics Inc.) and the Natural-Hip HA (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

SEP 19 1997

Re: K972393
Inter-Op™ HA Porous Acetabular System
Regulatory Class: II
Product Codes: LPH and MEH
Dated: June 25, 1997
Received: June 26, 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 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. 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.

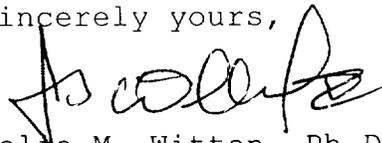
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

Page 3 - Lori Kleinschrodt Holder, RAC

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,



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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): Unknown K972393

Device Name: Inter-Op™ HA Porous Acetabular System

Indications For Use:

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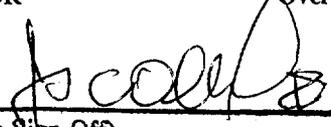
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number

Prescription Use X

OR

Over-The-Counter Use _____



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K972393

(Optional Format 1-2-96)