MAY 2 2 1997 K970705

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™ Porous Revision Shell with Sealable Screwholes.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9687
Date:	February 18, 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:	Metal-backed Acetabular Component
Trade/Proprietary Name:	Inter-Op™ Porous Revision Shell with Sealable Screwholes

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PRODUCT DESCRIPTION

The Inter-Op Porous Revision Shell with Sealable Screwholes is a hemispherical metal shell that is utilized with a snap-in polyethylene insert. The shell is manufactured from Ti-6Al-4V alloy and coated with Cancellous Structured Titanium™ (CSTi™). The insert is manufactured from ultra-high molecular weight polyethylene (UHMWPE) and is available in standard, hooded and hooded protrusio designs in order to address various clinical situations.

The Revision Shell with Sealable Screwholes is designed for screw application with nine screwholes allowing for screw placement into the ilium, ischium and pubis. Furthermore, those screwholes that are not utilized may be plugged after implantation thus limiting the potential for fibrous tissue growth into the shell upon cementless implantation or cement extrusion into the shell upon cemented application. Additionally, if wear of the polyethylene acetabular insert occurs, the hole plugs restrict the debris from migrating through the acetabular shell holes into the acetabulum.

The integrity of the locking mechanism of the Revision Shell 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

This device is intended to replace the acetabulum during total hip arthroplasty and may be implanted with or without bone cement. Diagnostic indications for use of this device 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 Porous Revision Shell with Sealable Screwholes is substantially equivalent to the APR Acetabular Shell (Sulzer Orthopedics Inc.), the S-ROM ZTT II Acetabular Shell with Apical Hole Plug (Johnson & Johnson Orthopedics), the P.F.C. Multi-Holed Porous Coated Acetabular Shell (Johnson & Johnson Orthopedics), the Duraloc 1200 Series Acetabular Cup (DePuy), and, the Trilogy Multi-Holed Shell (Zimmer).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1997

Mr. Shavawn Parduhn
Regulatory Affairs Associate
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K970705
Inter-Op™ Porous Revision Shell
with Sealable Screwholes
K970706
Inter-Op™ Porous Protrusio Shell
with Sealable Screwholes
Regulatory Class: II
Product Codes: LPH and LZO
Dated: February 25, 1997
Received: February 26, 1997

Dear Mr. Parduhn:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are 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 devices, 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.

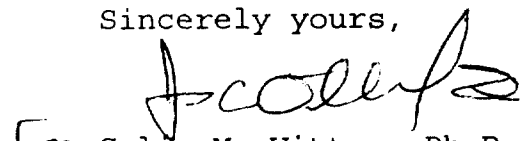
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,



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

Enclosures

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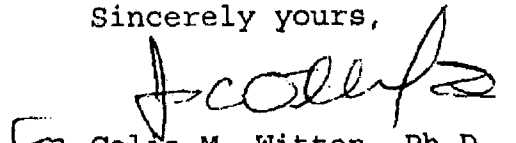

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): Unknown

Device Name: Inter-Op™ Porous Revision Shell with Sealable Screwholes

Indications For Use:

The Inter-Op Porous Revision Shell with Sealable Screwholes is a porous coated hemispherical shell that is used in conjunction with a snap-in acetabular insert manufactured from ultra-high molecular weight polyethylene (UHMWPE). This device is intended to replace the acetabulum during total hip arthroplasty and may be implanted with or without bone cement. Diagnostic indications for use of this device 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.

(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 K970705

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

(Optional Format 1-2-96)