AUG -3 1999

K974728

510(k) SUMMARY

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. Inter-Op Metasul Acetabular System.

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

Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

Classification Name: CFR 888.3330 - Hip joint metal/metal semiconstrained, with an uncemented acetabular component, prosthesis

Common/Usual Name: Acetabular insert and head component of a total hip replacement

Trade/Proprietary Name: Inter-Op Metasul Acetabular System

PRODUCT DESCRIPTION:

The Inter-Op Acetabular System is comprised of two components: (1) a polyethylene acetabular insert with an integral Metasul metal inlay (inner diameter), and (2) a Metasul femoral head.

Inter-Op Metasul Acetabular Insert

The Inter-Op Metasul Acetabular Insert is a hemispherical polyethylene component manufactured from UHMWPE (ASTM F648). The outer diameter of the insert is machined with locking features that mate with one of the previously cleared Inter-Op metallic acetabular shells.

The inner diameter which forms the bearing surface of the insert features a metallic Metasul inlay that is integrally locked to the polyethylene insert. The metal inlay is manufactured from Protasul®-21WF, a wrought forged CoCrMo alloy (ISO 5832). This inlay is polished to a mirror-finish and hot-pressed into the UHMWPE backing. Just prior to hot-pressing, two Protasul-10 (CoCr alloy, ASTM F562) pins are press fit into the design of the inlay to help provide added rotational stability. The Metasul inlay is designed for use only with the Metasul head component.

The Inter-Op Metasul Acetabular Insert component is available with outside diameters of 49mm to 81mm (in 2mm increments) with an inner diameter of 28mm.

Metasul Femoral Head

The Metasul Femoral Heads are manufactured from the same Protasul-21WF (CoCr, ISO 5832) material as the metal inlay of the acetabular component. The design incorporates a 12/14 morse type female taper with beveled face for ease of reduction intraoperatively. The female taper matches the 12/14 male taper used on Sulzer Orthopedics femoral stems.

The Metasul femoral heads are designed specifically to articulate with the Metasul inlay of the acetabular component. High precision manufacturing allows for optimal articulating surface

geometry (e.g., clearance between the Metasul head and the Metasul inlay). These devices are manufactured within tight tolerances because the success of the system is dependent on optimal performance at this articulating interface

The Metasul heads are available in 28mm diameter with four neck lengths: short (-4mm), medium (neutral), long (+4mm) and extra long (+8mm).

SPECIFIC DIAGNOSTIC INDICATIONS:

The Inter-Op Metasul Acetabular System is intended for use in cases of total hip replacement for treatment of the following:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, post traumatic arthritis or avascular necrosis and inflammatory degenerative 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 Inter-Op Metasul Acetabular System to the following preamendments predicate devices:

- McKee-Farrar Total Hip
- Ring Total Hip
- Sivash Total Hip

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 1999

Mitchell A. Dhority, RAC
Sr. Regulatory Affairs Specialist
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K974728
Trade Name: Inter-Op™ Metasul® Acetabular System
Regulatory Class: III
Product Code: KWA
Dated: May 20, 1999
Received: May 21, 1999

Dear Mr. Dhority:

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 control provisions of the Act. The general control 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. Furthermore, for questions regarding 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 at (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

Enclosure

510(k) Number (if known): K974728

Device Name: Inter-Op Metasul Acetabular System

Indications for Use:

The Inter-Op Metasul Acetabular System is intended for use in cases of total hip replacement for treatment of the following:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, post traumatic arthritis or avascular necrosis and inflammatory degenerative 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 K974728

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

(Optional Format 1-2-96)