DEC - 1 1999

K993569

510(k) SUMMARY

Sponsor:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Contact Person:	Mitchell Dhority, RAC Manager, Regulatory and Clinical Affairs
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis, 21 CFR 888.3358
Common/Usual Name:	Total Hip Prosthesis, Semi-constrained
Trade/Proprietary Name:	Sulzer Orthopedics APR Metasul Acetabular Inserts

PRODUCT DESCRIPTION

The APR Metasul Acetabular Insert is a modular metal-on-metal insert which is hemispherical in shape and has an outer diameter manufactured from polyethylene (UHMWPE, ASTM F648). The outer diameter of the insert is machined with locking features that mate with one of the previously cleared APR metallic acetabular shells.

The inner diameter which forms the bearing surface of this insert features a metallic Metasul inlay that is integrally locked to the polyethylene portion. The metal inlay is manufactured from Protasul®-21WF, a wrought forged CoCrMo alloy (ISO 5832-4, ISO 5832-12). 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 may be press fit into the design of the inlay to help provide added rotational stability. As a result of the strictly controlled tolerances of the inlay and in order to recognize the beneficial wear properties associated with this component, this insert is designed for use only with previously cleared Metasul head components.

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

INTENDED USE / DIAGNOSTIC INDICATIONS

The APR Metasul Acetabular Inserts are intended for use with the APR Acetabular Shells and Metasul femoral heads 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

Substantial equivalence is based on a direct comparison to the commercially APR Acetabular System and Inter-Op Metasul Acetabular System. The fundamental scientific technologies

incorporated into these two products has not changed in the APR Metasul Acetabular Insert. Based on conformance with the design control requirements as specified in 21 CFR 820.30 and similarities in design, materials, sterilization, method of manufacture, intended use and indications for use, we believe that the APR Metasul Acetabular Insert is substantially equivalent to the previously cleared APR Acetabular System and Inter-Op Metasul Acetabular System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mitchell A. Dhority, RAC
Manager, Regulatory and Clinical Affairs
Sulzer Medica
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K993569
Trade Name: APR Metasul Acetabular Insert
Regulatory Class: III
Product Code: KWA
Dated: November 15, 1999
Received: November 16, 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 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.

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,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993569

Device Name: APR Metasul Acetabular Inserts

Indications for Use:

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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 K993569

Prescription Use X **OR** **Over-the Counter Use** ___

(Optional Format 1-2-96)