K993943

DEC - 2 1999

510(k) SUMMARY

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 MS-30 Femoral Stem.

Manufacturer:	Sulzer Orthopedics Ltd. Grabenstrasse 25 CH 6341 Baar, Switzerland
US Designated Agent:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	September 7, 1999
Contact Person:	Mitchell A. Dhority, RAC Manager, Regulatory and Clinical Affairs
Classification Name:	21 CFR Part 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Common/Usual Name:	Cemented Femoral Stem Component
Trade/Proprietary Name:	Sulzer Orthopedics MS-30 Femoral Stem

PRODUCT DESCRIPTION

Femoral Stem

The MS-30 is a highly polished metallic femoral component manufactured from forged stainless steel alloy (Protasul S30, ISO 5832-9). It is available in six sizes. The stem features a three dimensional conical wedge shape with rounded edges to aid in rotational stability, self centering in the femoral canal, and creation of a favorable cement mantle. The proximal aspect of the stem has a male 12/14 type morse taper for attachment of a Sulzer Orthopedics metallic or ceramic femoral head. The most distal aspect of the stem has a small pilot hole for attachment of a distal centralizer. The stem is intended for cemented use only.

Distal Centralizer

The MS-30 also features an optional distal centralizer which is manufactured from PMMA (ISO 5833-1) with a wrought CoCr alloy locating pin (Protasul 10, ISO 5832-6). The pin provides for slip fit connection to the distal stem. The centralizer is conically shaped with a small proximal tab that prevents rotation about the stem upon insertion into the canal.

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SPECIFIC DIAGNOSTIC INDICATIONS

The MS-30 Femoral Stem is intended for cemented use in treatment of the following:

1. Advanced wear of the joint due to degenerative, posttraumatic or rheumatic diseases.
2. Fractures or vascular necroses.
3. Status following earlier operations, such as joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty of total hip prosthesis (THP).

SUBSTANTIAL EQUIVALENCE

The MS-30 Femoral Stem is similar to the following commercially available devices in terms of intended use, materials and general design:

- DePuy Endurance Polished Stem
- Howmedica Osteonics Exeter Hip Stem
- Zimmer VerSys Cemented CT Hip Stem
- Zimmer VerSys Heritage Hip Stem

Testing/analysis indicated that the device would survive physiologic loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 1999

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

Re: K993043
Trade Name: APR Metasul Acetabular Insert
Regulatory Class: II
Product Code: LZO
Dated: September 9, 1999
Received: September 10, 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): 993043

Device Name: MS-30 Femoral Stem

Indications for Use:

The MS-30 Femoral Stem is intended for cemented use in treatment of the following:

1. Advanced wear of the joint due to degenerative, posttraumatic or rheumatic diseases.
2. Fractures or vascular necroses.
3. Status following earlier operations, such as joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty of total hip prosthesis (THP).

MRO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993043

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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