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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 line additions to the Inter-Op™ Durasul™ Acetabular components and CoCr Femoral Heads.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	September 17, 1999
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 Inter-Op™ Durasul™ Acetabular Inserts and CoCr Femoral Heads

PRODUCT DESCRIPTION

The Sulzer Orthopedics Inter-Op Durasul Acetabular Inserts were originally cleared via 510(k) K983509. The purpose of the present submission is to gain notice of substantial equivalence for line additions to these previously cleared insert components and corresponding metallic heads. More specifically, this includes decreased thicknesses (down to 5mm) of the previously cleared Inter-Op Durasul Standard Acetabular Insert design for use with 28, 32, 38mm and 46mm CoCr femoral heads.

SPECIFIC DIAGNOSTIC INDICATIONS

Diagnostic indications for use of this device include:

- 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

The Inter-Op Durasul Standard Acetabular insert is substantially equivalent and identical in intended use, function, material and general overall design to those products cleared under K983509. These are modular components that are manufactured from the same Durasul cross-linked polyethylene, interface with the same Inter-Op Acetabular Shells and metallic heads and are used to resurface the acetabulum during total hip arthroplasty in the same indications. The main difference is the decreased polyethylene insert thickness (down to 5mm) and increase in diameter of the corresponding head sizes that will be offered.

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Wear, contact stress, fatigue, and locking mechanism integrity testing all indicated that these line additions would perform as intended and similar to legally marketed products. The results of *in vitro* wear tests have not been shown to correlate with clinical wear mechanisms

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2000

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

Re: K993259
Trade Name: Sulzer Orthopedics Inter-Op™ Durasul™ Acetabular Inserts and CoCr Femoral Heads
Regulatory Class: II
Product Code: LPH and JDI
Dated: January 14, 2000
Received: January 18, 2000

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. 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for 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): K993259

Device Name: Inter-Op Durasul Acetabular Components/CoCr Heads – Line Additions

Indications for Use:

The Inter-Op Durasul Acetabular Components and CoCr Femoral Heads are intended for use in treatment of the following:

1. Advanced joint destruction resulting from degenerative, posttraumatic or rheumatoid arthritis.
2. Fracture or avascular necrosis of the femoral head.
3. Failed previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemiarthroplasty and total hip replacement.

(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 K993259

Prescription Use ✓ **OR** **Over-the Counter Use** No

(Optional Format 1-2-96)