K983509

FEB 3 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 Inter-Op™ DURASUL™ Acetabular Insert.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	February 3, 1999
Contact Person:	Mitchell Dhority, RAC Manager, Regulatory 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 Insert

PRODUCT DESCRIPTION

Sulzer Orthopedics currently markets a polyethylene shell liner (insert) in conjunction with its Inter-Op Acetabular System. The UHMWPE insert was originally cleared via 510(k) K955033 and is available in three styles, all of which mate with various shell designs in the system.

The purpose of this submission is to describe a different UHMWPE treatment process that was developed and patented by Massachusetts General Hospital (MGH) and Massachusetts Institute of Technology (MIT). This treatment produces a highly cross-linked polyethylene and reduces free radicals that can lead to oxidative degradation. This in turn provides a highly wear resistant surface which has been demonstrated through hip simulation.

Sulzer Orthopedics has licensed this process for use in the manufacture of Inter-Op acetabular inserts. Sulzer Orthopedics does not intend to change the intended use of this device, nor do we intend to alter the basic geometrical design of the three insert styles. Moreover, while there is a change in process to enhance the wear properties of UHMWPE, there is no change to the raw material (GUR 1150/1050 conforming to ASTM F 648).

Sulzer Orthopedics intends to make marketing claims with regard to wear properties based on improved performance demonstrated by comparative hip simulator test results. DURASUL inserts were tested under identical conditions and compared to inserts manufactured and treated according to current processes (CONTROL). Undetectable wear was noted over 5 million cycles as compared to a steady average wear rate of approximately 12 mg/million cycles for the CONTROL inserts. The results of *in vitro* wear tests have not been shown to correlate with clinical wear mechanisms.

SPECIFIC DIAGNOSTIC INDICATIONS

The DURASUL acetabular insert is a snap-in acetabular shell liner that is manufactured from ultra-high molecular weight polyethylene (UHMWPE). The insert is available in three styles and is intended to be used in conjunction with an Inter-Op acetabular shell to replace the acetabulum during total hip arthroplasty. Inter-Op acetabular components (shell/insert combination) may be implanted with or without bone cement.

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 acetabular insert is substantially equivalent in function, material and overall design to most currently marketed shell liners. It is a modular component that is manufactured from cross-linked polyethylene and is used to resurface the acetabulum during total hip arthroplasty. The major difference between the DURASUL insert and other commercially available designs is that it is cross-linked by electron beam radiation under melting conditions rather than gamma radiation. It is also irradiated at a slightly higher effective dose than the typical sterilization dose used in the industry.

Sulzer Orthopedics is unaware of any other orthopedic manufacturer that uses this process for their polyethylene components. Therefore, substantial equivalence is based upon comparison of the DURASUL acetabular insert to Sulzer Orthopedics' currently available Inter-Op design. The following summarizes the similarities between the two:

- The DURASUL acetabular insert (manufactured using the WIAM process) has the same intended use as Sulzer Orthopedics currently available acetabular inserts (manufactured using standard polyethylene).
- The geometrical design of the DURASUL acetabular insert is essentially the same as the currently available Inter-Op insert.
- The DURASUL insert and the currently available insert are both manufactured from UHMWPE that is subsequently cross-linked by irradiation. Both the standard and WIAM treated material conform to ASTM F 648, even after cross-linking. They both also conform to the FDA draft guidance document.
- Both the standard and WIAM material exhibit similar lamellar networks. The cross-link densities are also similar: 0.13mol/dm^3 for the standard gamma irradiated material as opposed to 0.18mol/dm^3 for the WIAM material.
- Although the wear performance of the WIAM processed material is much improved over the standard material, other performance characteristics are essentially the same. Neither the WIAM nor standard process compromised the fatigue or creep behavior of the inserts under physiological testing. Likewise, the locking strength of the shell/liner interface was the same for the DURASUL insert as compared to the currently available device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 1999

Ms. Shavawn Evans Parduhn
Regulatory Affairs Specialist
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K983509
Trade Name: Inter-Op™ Acetabular System, Durasul™ Acetabular Insert
Regulatory Class: II
Product Codes: JDI and LPH
Dated: January 4, 1999
Received: January 5, 1999

Dear Ms. Parduhn:

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,

for 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): K983509

Device Name: Inter-Op DURASUL Acetabular Insert

Indications For Use:

The DURASUL acetabular insert is a snap-in acetabular shell liner that is manufactured from ultra-high molecular weight polyethylene (UHMWPE). The insert is available in three styles and is intended to be used in conjunction with an Inter-Op acetabular shell to replace the acetabulum during total hip arthroplasty. Inter-Op acetabular components (shell/insert combination) may be implanted with or without bone cement.

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- those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- 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)

Prescription Use yes X OR Over-The-Counter Use No

(Optional Format 1-2-96)

Russell L. Hayes for CWL

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 98 3509