

JAN 28 1999

K 983592

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 Sysorb Interference Screw.

**Submitter/
Author. Rep.:** Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717
(512) 432-9900

Manufacturer: Sulzer Orthopedics Ltd.
Grabenstrasse 25
CH-6341 Baar, Switzerland

Date: October 8, 1998

Contact Person: Mitchell A. Dhority, RAC
Manager, Regulatory Affairs

Classification Name: 21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener

Common/Usual Name: Resorbable interference screw

Trade/Proprietary Name: Sulzer Orthopedics Sysorb Interference Screw

PRODUCT DESCRIPTION

The Sulzer Orthopedics Sysorb Interference Screws are a bioresorbable interference screw used in attachment of autologous tendon transfers in cruciate ligament reconstruction. The Sysorb interference screws are manufactured from the bioresorbable material Poly (D,L-Lactide) (Resomer R208), an amorphous polymer derivative of lactic acid. The screw provides an initial interference fit fixation of the tissue graft and resorbs over time as the graft is naturally incorporated into the surrounding structure.

The Sysorb Interference Screw uses a nearly symmetrical thread profile which takes into account both the strength of the material and the relative strength of cancellous bone. The design also allows the screw to be introduced without drilling or tapping. A continuous "turbine" shaped driving feature allows torque to be applied along the complete length of the screw upon implantation, thus minimizing the potential for fracture of the implant.

SPECIFIC DIAGNOSTIC INDICATIONS

The Sulzer Orthopedics Sysorb Interference Screws are intended for use in tibial and femoral fixation (primary anchorage) of the autologous tendon-transplants as it is used in the reconstruction of the cruciate ligaments of the human knee.

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SUBSTANTIAL EQUIVALENCE

The Sulzer Orthopedics Sysorb Interference Screws are similar to the following competitive, commercially available resorbable interference screws:

- Smith & Nephew (Acufex) Endo-Fix
- Instrument Makar Biologically Quiet
- Arthrex Bio-Interference
- Linvatec Bioscrew



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983592
SYSORB Resorbable Interference Screw
Regulatory Class: II
Product Codes: MAI, HWC, and GAT
Dated: January 12, 1999
Received: January 14, 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.

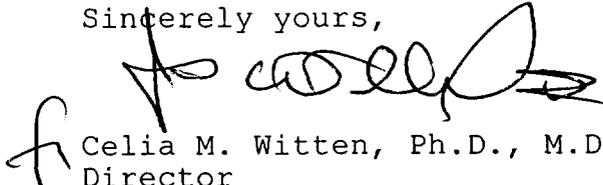
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Mitchell A. Dhority

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,



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): 6983592

Device Name: Sulzer Orthopedics Sysorb Interference Screws

Indications For Use:

The Sulzer Orthopedics Sysorb Interference Screws are intended for use in the following diagnostic indications:

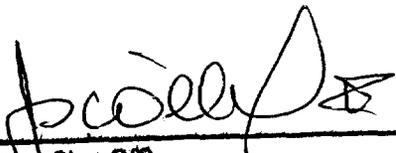
1. Tibial and femoral fixation (primary anchorage) of the autologous tendon-transplants as it is used in the reconstruction of the cruciate ligaments of the human knee.

(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 _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 6983592