DEC 1 3 2001

510(k) SUMMARY

K013935

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 Ltd. Allofit Acetabular System 32mm Alpha Durasul Inserts.

Manufacturer:	Sulzer Orthopedics Ltd. Grabenstrasse 25 CH-6341 Baar, Switzerland
US Distributor:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	November 27, 2001
Contact Person:	Mitchell A. Dhority Director, Regulatory & Clinical Affairs
Classification Name:	21 CFR Part 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Common/Usual Name:	Acetabular Insert Components
Trade/Proprietary Name:	Allofit Acetabular System 32mm Alpha Durasul Inserts

PRODUCT DESCRIPTION

This Special 510(k) submission seeks to obtain clearance for addition of the Allofit 32mm Alpha Durasul Inserts to the existing, previously cleared (K003578) Allofit 28mm Alpha Durasul Insert product line. The only difference from the existing product is the internal diameter of the insert (32mm vs. 28mm).

There are also no changes to the other previously cleared components of the system which are used in conjunction with the inserts (e.g, acetabular shells, dome hole covers, screw hole covers, instrumentation).

The Allofit 32mm Alpha Durasul inserts incorporate the same general design features as the existing, previously cleared Allofit 28mm Alpha Durasul insert components and Allofit 32mm Alpha inserts (standard Sulene polyethylene). The inserts are snapped into the respective Allofit titanium shell intraoperatively. A peripheral locking mechanism holds the insert within the shell. A peg shaped eminence at the apex of the insert slips into the dome hole of the shell and provides further stability of the insert within the shell. Upon impaction into the shell, two short spikes in the dome of the metallic shell minimally penetrate the polyethylene insert, providing additional resistance to rotation. Both a standard and hooded insert configuration will continue to be offered.

The Allofit 32mm Alpha Durasul inserts will also use the same materials as the previously cleared devices (ISO 5834-1/2). The Durasul material is identical to that which was previously

characterized and cleared for use in the Allofit 28mm Alpha Durasul Inserts.

SPECIFIC DIAGNOSTIC INDICATIONS

There have been no changes in the diagnostic indications from the previously cleared components as a result of this line addition.

Components of the Allofit Acetabular System are intended for use 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 hip arthroplasty.

SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on comparison to the previously cleared Allofit 28mm Alpha Durasul Inserts. The fundamental scientific technologies incorporated in this previously cleared design have not changed in this product line addition. The only difference in the existing Allofit Alpha Durasul Insert components and this line addition is the internal diameter (32mm vs. 28mm).

Based on conformance with the design control requirements as specified in 21 CFR 820.30 and similarities in design, materials, sterilization, packaging, instrumentation, intended use and indications for use, we believe that the Allofit 32mm Alpha Durasul Inserts are substantially equivalent to the previously cleared Allofit 28mm Alpha Durasul Inserts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2001

Mr. Mitchell A. Dhority
Director, Regulatory & Clinical Affairs
Sulzer Orthopedics Incorporated
9900 Spectrum Drive
Austin, Texas 78717

Re: K013935
Trade Name: Allofit Acetabular System/32mm Alpha Inserts
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: November 27, 2001
Received: November 28, 2001

Dear Mr. Dhority:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

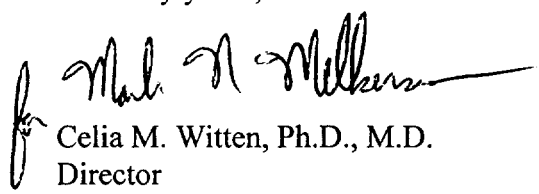
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013935

Device Name: Allofit Acetabular System – Alpha 32mm Durasul Inserts

Indications for Use:

Components of the Allofit Acetabular System are intended for use 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 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 X OR Over-The-Counter Use

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013935