K002335

OCT 2 5 2000

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® Natural-Knee® II DURASUL™ Tibial Inserts and DURASUL™ Patella.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	July 31, 2000
Contact Person:	Mitchell A. Dhority Manager, Regulatory & Clinical Affairs
Classification Name:	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer 21 CFR 888.3560
Common/Usual Name:	Knee Prosthesis, Semiconstrained
Trade/Proprietary Name:	Natural-Knee® II DURASUL™ Tibial Inserts Natural-Knee® II DURASUL™ Patella

PRODUCT DESCRIPTION

The Natural-Knee II System is a total knee replacement system that was originally cleared for use via K936159 on May 22, 1995. The tibial component is a modular assembly consisting of a polyethylene insert that is intraoperatively snapped into one of the system's metal baseplates. The insert is available in three styles and is manufactured from ultra-high molecular weight polyethylene (UHMWPE). The patellar component is an all-polyethylene component, also manufactured from UHMWPE. These UHMWPE components are sterilized by gamma radiation (2.5-4.1 Mrads) in an oxygen-depleted environment.

Sulzer Orthopedics has received marketing clearance for a new UHMWPE treatment process applied to acetabular inserts. This process, known as Warm Irradiated Adiabatic Melting, or WIAM, involves irradiating the polyethylene using electron beam (e-beam), subsequently melt annealing the material to eliminate any free radicals generated during irradiation and sterilizing the components using ethylene oxide gas. The trade name for UHMWPE that has been WIAM processed is Durasul™.

Sulzer Orthopedics now wishes to apply the WIAM process to the Natural-Knee II UHMWPE knee components listed above. Sulzer Orthopedics does not propose to change the intended use of this device, nor do we intend to alter the basic geometrical design of the components. This is a change to an UHMWPE processing technique only and is not expected to affect the performance of the design.

SPECIFIC DIAGNOSTIC INDICATIONS

The Natural-Knee II System is intended for replacement of the knee joint during total knee arthroplasty. The Durasul tibial insert and the Durasul patella are polyethylene components of the Natural-Knee II System. The Durasul tibial insert is used in conjunction with one of the system's metal baseplates for resurfacing of the tibia. The Durasul patella is an all-polyethylene component for resurfacing of the patella.

Natural-Knee II Durasul components are intended for use only with bone cement. Diagnostic indications include:

1. Patient conditions of noninflammatory degenerative joint disease (e.g., osteoarthritis, avascular necrosis) or inflammatory degenerative joint disease (e.g., rheumatoid arthritis).
2. Correctable valgus-varus deformity and moderate flexion contracture.
3. Those patients with failed previous surgery where pain, deformity or dysfunction persists.
4. Revision of previously failed knee arthroplasty.

SUBSTANTIAL EQUIVALENCE

The Natural-Knee II Durasul tibial insert and all-poly patella are substantially equivalent in function, material and overall design to most currently marketed polyethylene articulating knee components. The major difference between the Durasul components and other commercially available designs is that they are cross-linked by electron beam radiation rather than gamma radiation and are subsequently melt-annealed.

Sulzer Orthopedics is unaware of any other orthopedic manufacturer that uses this process as applied to knee polyethylene components. Therefore, substantial equivalence is based upon comparison to Sulzer Orthopedics currently marketed Natural-Knee II design as outlined below:

Intended Use

The Natural-Knee II Durasul tibial inserts and all-poly patella (manufactured using the WIAM process) have the same intended use as Sulzer Orthopedics currently available tibial inserts and patella.

Design

The geometrical design of the Durasul tibial insert is the same as the currently available Natural-Knee II insert. Likewise, the Durasul all-poly patella is geometrically identical to the current Natural-Knee II all-poly patella.

Material

The Durasul components and the currently available Natural-Knee II components are both manufactured from UHMWPE that is subsequently cross-linked by irradiation. Both the standard and WIAM treated material conform to the ASTM F 648, even after cross-linking. They both also conform to the FDA draft guidance document.

Performance

The stability of the Natural-Knee II Durasul components was determined by evaluating tibiofemoral and patellofemoral constraint. Testing showed that application of Durasul to the

Natural-Knee II design provides adequate constraint when subjected to shear forces experienced by the knee as established by Greenwald *et al.*

The locking mechanism of the tibial component was evaluated through peel-out testing of the tibial insert from the baseplate. Results showed that the attachment strength of the Natural-Knee II Durasul tibial component is capable of withstanding the maximum shear forces experienced by the knee as reported by Greenwald *et al.*

Simulator testing indicated that the Durasul components provide equivalent performance in terms of creep deformation with a definite advantage of less deformation on the lateral condyle as compared to the conventionally packaged, currently marketed tibial inserts.

Wear testing indicated that the Durasul material had dramatically improved wear resistance in comparison to the conventionally packaged, currently marketed tibial inserts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2000

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

Re: K002335
Trade Name: Natural-Knee II System – Durasul Tibial Inserts and Durasul All-Poly Patella
Regulatory Class: II
Product Code: JWH
Dated: July 31, 2000
Received: August 1, 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 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 at (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, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002335

Device Name: Natural-Knee® II DURASUL Tibial Insert and DURASUL All-Poly Patella

Indications for Use:

The Natural-Knee II System is intended for replacement of the knee joint during total knee arthroplasty. The Durasul tibial insert and the Durasul patella are polyethylene components of the Natural-Knee II System. The Durasul tibial insert is used in conjunction with one of the system's metal baseplates for resurfacing of the tibia. The Durasul patella is an all-polyethylene component for resurfacing of the patella.

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4. Revision of previously failed knee arthroplasty.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devic
510(k) Number K002335

Prescription Use X OR Over-The-Counter Use _____