JUN 11 1999

K991143

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® Magna-ROM™ 21 Knee System.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	April 1, 1999
Contact Person:	Mitchell A. Dhority Manager, Regulatory Affairs
Classification Name:	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer 21 CFR 888.3560
Common/Usual Name:	Knee Prosthesis, Partially Constrained
Trade/Proprietary Name:	Magna-ROM™ 21 Knee System

SPECIFIC DIAGNOSTIC INDICATIONS

The Magna-ROM 21 Knee System is intended for replacement of the knee joint during total knee arthroplasty. Specific diagnostic indications include:

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

Components of the Magna-ROM system are intended for use only with bone cement.

PRODUCT DESCRIPTION

The Magna-ROM 21 Knee System is a total primary knee system that was designed to provide a better proportional fit for people of Asian descent. Studies of Japanese and Chinese anatomy have shown that the shape of the knee is slightly different than the European or American knee, particularly in the smaller adult. Results of a study in which Sulzer Orthopedics examined CT-scan data from 52 Japanese patients showed that the anterior/posterior depth is smaller for the Asian knee as compared to the American or European knee, and the medial/lateral width is larger.

Components of the Magna-ROM 21 Knee System are basically the same as conventional knee components. However, based on the data collected from the CT-Scan study, dimensions of the Magna-ROM components were scaled to address those patients who exhibit the need (through preoperative templating) for somewhat wider mediolateral coverage and smaller

anteroposterior coverage than conventional knee components can provide. The size range for the Magna-ROM system also includes proportionally smaller components than conventional knee components because of the smaller adult sizes in the Asian population.

The design features for each Magna-ROM component are described below.

Femoral Component

The femoral component is a total condylar prosthesis that is manufactured from cast CoCr alloy. It has an anatomical design and will be offered in five sizes in both left and right configurations. The interior box of the femoral component is porous coated with Sulzer Orthopedics™ Cancellous Structured Titanium™ (CSTi™) for potentially enhanced cement fixation.

The femoral component incorporates a deep patellar groove that conforms to the geometry of the patella prosthesis and provides for rolling/sliding articulation. The condylar geometry is rounded in both the anterior/posterior and medial/lateral planes to enhance contact area with the polyethylene tibial insert. The posterior condyles are slightly longer than conventional femoral components to facilitate optimum range of motion.

Tibial Component

The tibial component consists of a metal baseplate that is manufactured from cast Ti-6Al-4V alloy that is used in conjunction with a snap-in polyethylene insert. The tibia component is a symmetric design, eliminating the need for left and right configurations.

The tibia baseplate will be offered in five sizes and has a wing-shaped keel for enhanced fixation within the intramedullary canal. Rotational stability is provided by two posterior fixation pegs. The underside of the baseplate, with the exception of the keel, is porous coated with CSTi for potentially enhanced cement fixation. Two screwholes are provided for the possible use of bone screws, if desired by the surgeon.

Tibial inserts will be offered in four thicknesses (6mm to 13mm) for each size and are designed with a snap-lock mechanism for attachment to the baseplate.

The insert comes in two styles, both of which are designed to preserve the posterior cruciate ligament PCL. The cruciate supplementing design is for those patients with a weaker PCL and/or soft tissue laxity. Resistance to anterior and posterior subluxation is supplied by a moderately constraining surface geometry. This design yields up to 120° of flexion, as determined by CAD kinematic overlay analysis.

The cruciate sparing design will be used for those patients with good ligament support. This style has slightly larger posterior radii. This, along with the longer posterior condyles of the femoral component, facilitates a larger range of motion (up to 135° of flexion).

Patella

The patella prosthesis is a cemented all-polyethylene component and comes in two styles: a round patella, which is recessed in the bone, and an offset patella, which utilizes a surface technique. The offset patella is slightly elliptical in shape and the crest is medial of center to more closely replicate the natural anatomy. Three sizes of each style will be available and may be matched with any size femoral component.

SUBSTANTIAL EQUIVALENCE

The Magna-ROM 21 Knee System is substantially equivalent to Sulzer Orthopedics Natural-Knee II System and Apollo Knee System.

The stability of the Magna-ROM 21 Knee components was determined by evaluating tibiofemoral and patellofemoral constraint. Testing showed that this design provides adequate constraint when subjected to shear forces experienced by the knee as established by Greenwald et al.

Tibial baseplate fatigue and insert attachment strength were evaluated and found to be comparable to a commercially available device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1999

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

Re: K991143
Trade Name: Magna-Rom™ 21 Knee System
Regulatory Class: II
Product Code: JWH
Dated: April 2, 1999
Received: April 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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. The thinnest tibial insert available is the nominal "Size 00/0, 9mm" insert, which has a minimum polyethylene thickness under the condyles of 6.0mm.

2. This device may not be labeled or promoted for non-cemented use.

3. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

4. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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): K991143

Device Name: Magna-ROM™ 21 Knee System

Indications For Use:

The Magna-ROM 21 Knee System is intended for replacement of the knee joint during total knee arthroplasty. Components of the Magna-ROM system are intended for use only with bone cement. Specific diagnostic indications include:

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

510(k) Number K991143

Prescription Use Yes OR Over-The-Counter Use No