OCT - 1 1997

K972501

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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 Apollo™ Revision/Constrained Knee System.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	July 1, 1997
Contact Person:	Jacquelyn Hughes 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:	Apollo™ Revision/Constrained Knee System

PRODUCT DESCRIPTION

The Apollo™ Revision/Constrained Knee System is a non-porous total knee replacement intended for primary and revision knee surgeries. The components are intended for resurfacing of the knee joint where the posterior cruciate ligament is absent, deficient, or has been removed at the time of surgery. The system is a semiconstrained design and both medial and lateral collateral ligaments must be intact.

The Apollo Revision/Constrained Knee femoral component is manufactured from cobalt chromium/molybdenum alloy (CoCr) with seperate left and right components. Femoral spacers manufactured from Ti-6Al-4V are also available for use with the Apollo Revision/Constrained Knee femoral component.

The Apollo Revision/Constrained Knee tibial components include a baseplate, spacers, and polyethylene insert. The tibial components are also symmetrical in design, eliminating the need for left/right orientations. The tibial baseplate and tibial spacers is manufactured from Ti-6Al-4V. The tibial inserts are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPe). A Ti-6Al-4V pin passing vertically from the constrained condylar (high medial/lateral constraint) eminence of the tibial insert to the tibial baseplate provides additional stability.

The Apollo Revision/Constrained Knee System is to be used with the Apollo all-poly patellar components.

The Natural-Knee II Revision Stems may be used with either the Apollo Revision/Constrained Knee System femoral or tibial components.

This device is intended for use with the following previously cleared devices:

- Apollo All-Poly Elliptical Patella
- Apollo PS All-Poly Tibia
- Apollo Posterior Stabilized (PS) Tibial Insert and Apollo Tibial Baseplate
- Apollo All-Poly Single-Lug Patella
- Natural-Knee II Revision Femoral Stems

The Apollo Revision/Constrained Knee Tibial Baseplate may also be used with the Apollo Congruent Tibial Insert. The Apollo Congruent Tibial Insert is **not** compatible with the Apollo Revision/Constrained Knee Femoral Component.

SPECIFIC DIAGNOSTIC INDICATIONS

The Apollo™ Revision/Constrained Knee System is intended use in the following diagnostic indications:

1. Patient conditions, including but not limited to, inflammatory degenerative joint disease (e.g., rheumatoid arthritis) and noninflammatory degenerative joint disease (e.g., osteoarthritis, avascular necrosis).
2. Correctable valgus-varus deformity and moderate flexion contracture.
3. Those patients with failed previous surgery where pain, deformity, or dysfunction persist.
4. Revision of previously failed knee arthroplasty.

The Apollo™ Revision/Constrained Knee System is intended only for use with bone cement in the United States. Uncemented use of the Apollo™ Revision/Constrained Knee System is considered to be investigational in the United States. This device is intended for single use only.

SUBSTANTIAL EQUIVALENCE

The Apollo™ Revision/Constrained Knee System is substantially equivalent to the Apollo PS Knee System (Sulzer Orthopedics), the Kinemax Plus Superstabilizer (Howmedica), and the PFC TC3 (Johnson & Johnson).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 1997

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

Re: K972501
Apollo Revision/Constrained Knee System
Regulatory Class: II
Product Code: JWH
Dated: July 2, 1997
Received: July 3, 1997

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). 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 "11 mm" sized insert, which has a minimum polyethylene thickness under the condyles of 8.00 mm.

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): K972501

Device Name: Apollo™ Revision/Constrained Knee System

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972501

Prescription Use X OR Over-The-Counter Use _____

(Optional Format 1-2-96)