K982903

OCT 21 1998

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 Fluted Stems.

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

Date: August 11, 1998

Contact Person: Mitchell A. Dhority, RAC
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: Sulzer Orthopedics Fluted Stems

PRODUCT DESCRIPTION

The Sulzer Orthopedics Fluted Stems, manufactured from forged or wrought Titanium alloy (ASTM F620 or F136, respectively), fit into the intermedullary canal of either the femur or tibia and provide additional implant stability. The stems are available in straight or offset versions in a variety of lengths and diameters. The flutes ensure rotational stability. The stems have been designed with male taper mechanisms which are capable of mating with the stem boss of the components. Rotational stability is afforded by the key feature at the base of the taper. Further assurance of stem-taper connection to the mating component is provided by a small set screw. This device is intended for use with the following devices:

- Natural-Knee II Revision Femoral Component
- Natural-Knee II Constrained Femoral Component
- Apollo Revision/Constrained Knee Femoral Component and Tibial Baseplate

SPECIFIC DIAGNOSTIC INDICATIONS

The Sulzer Orthopedics Fluted Stems are intended for cemented 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.

SUBSTANTIAL EQUIVALENCE

The Sulzer Orthopedics Fluted Stems are substantially equivalent to the fluted stems used with the Maxim Constrained Knee (Biomet), the Coordinate Revision Knee (DePuy), Kinemax Plus Super Stabilizer (Howmedica), and the PFC - TC3 (Johnson and Johnson).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

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

Re: K982903
Sulzer Orthopedics Fluted Stems
Regulatory Class: II
Product Code: JWH
Dated: August 17, 1998
Received: August 18, 1998

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

2. 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.

3. 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,

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): K982903

Device Name: Sulzer Orthopedics Fluted Stems

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 K982903

Prescription Use X OR Over-The-Counter Use _____

(Optional Format 1-2-96)