

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 Apollo Constrained/Revision Knee Tibial Baseplate Stem Plugs.

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

Date: October 16, 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 Apollo Constrained/Revision Knee System
Tibial Baseplate Stem Plugs

PRODUCT DESCRIPTION

The Sulzer Orthopedics Apollo Revision/Constrained Knee Tibial Baseplate Stem Plugs ("plug"), manufactured from wrought (ASTM F136) titanium alloy, are designed to fit into the female connection of the baseplate keel when no tibial stem component is used. The plug is connected to the baseplate component via a small set screw. The plugs therefore act to restrict the flow of bone cement into the baseplate component. This component is intended for use with the Apollo Revision/Constrained Knee Tibial Baseplate.

SPECIFIC DIAGNOSTIC INDICATIONS

The tibial baseplate stem plugs 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 stem plugs used with the Maxim Constrained Knee (Biomet), the Coordinate Revision Knee (DePuy), Kinemax Plus Super Stabilizer (Howmedica), and the PFC - TC3 (Johnson and Johnson).

Analysis indicated that the device would survive physiologic loading.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

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

Re: K983733
Trade Name: Sulzer Orthopedics Apollo
Constrained/Revision Knee System
Tibial Baseplate Stem Plugs
Regulatory Class: II
Product Code: JWH
Dated: October 21, 1998
Received: October 22, 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). 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.

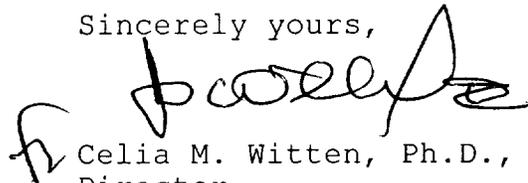
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 (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): K983733

Device Name: Apollo Revision/Constrained Knee System Tibial Baseplate Stem Plug

Indications For Use:

The tibial baseplate stem plugs are 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.

(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 K983733

Prescription Use X

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)