k021578

AUG 0 9 2002

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Inc. Natural Knee II System CoCr Tibial Baseplate.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	May 13, 2002
Contact Person:	Frances E. Harrison Manager, Regulatory Projects
Classification Name:	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis, 21 CFR 888.3560
Common/Usual Name:	Knee Prosthesis, Partially Constrained
Trade/Proprietary:	Natural-Knee® II System CoCr Tibial Baseplate

PRODUCT DESCRIPTION

The CoCr tibial baseplate, manufactured from cast CoCr alloy (ASTM-F-75), is a non-porous, stemmed configuration and intended for cemented use only. The CoCr tibial baseplate is anatomic and asymmetric in design, available in sizes 00-5 and left and right configurations.

SPECIFIC DIAGNOSTIC INDICATIONS

The Natural-Knee II CoCr Tibial Baseplate is a primary component intended for cemented use only in total knee arthroplasty in skeletally mature individuals for treatment of the following:

- Patient conditions of Noninflammatory Degenerative Joint Disease (NIDJD); e.g., avascular necrosis, osteoarthritis and Inflammatory Joint Disease (IJD); e.g, rheumatoid arthritis.
- Correctable valgus-varus deformity and moderate flexion contracture.

SUBSTANTIAL EQUIVALENCE

The Natural Knee II CoCr Tibial Baseplate is to the following commercially available in devices in terms of general design, intended use and indications for use:

- Natural Knee II System Non-porous Stemmed Tibial Baseplate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 9 2002

Ms. Frances E. Harrison, RAC
Manager, Regulatory Projects
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K021578
Trade/Device Name: Natural-Knee II CoCr Tibial Baseplate
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: May 13, 2002
Received: May 14, 2002

Dear Ms. Harrison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

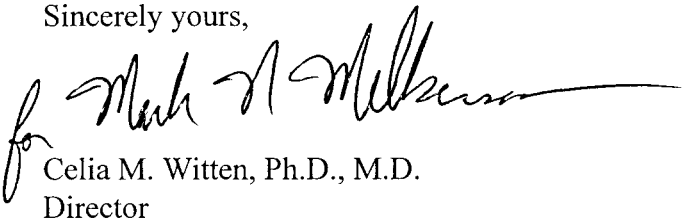
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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): K021578

Device Name: Natural-Knee II System

Indications for Use:

The Natural-Knee II CoCr Tibial Baseplate is a primary component intended for cemented use only in total knee arthroplasty in skeletally mature individuals for treatment of the following:

- Patient conditions of Noninflammatory Degenerative Joint Disease (NIDJD); e.g., avascular necrosis, osteoarthritis and Inflammatory Joint Disease (IJD); e.g, rheumatoid arthritis.
- Correctable valgus-varus deformity and moderate flexion contracture.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use

for Mark N Milhern (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021578