

JUN 9 1999

K991106

510(k) Summary
P.F.C. Sigma Porous Modular Keel Tibial Tray

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581

A. Contact Person:

Janet G. Johnson, RAC
Senior Regulatory Associate
(219) 372-7484

B. Device Information:

Proprietary Name: P.F.C. Sigma Porous Modular Keel Tibial Tray
Common Name: Tibial Tray
Classification Name: Knee Joint Patellofemorotibial polymer/metal/polymer
semi-constrained cemented prosthesis
Regulatory Class: Class II, per 21 §CFR 888.3560
Product Code: 87 JWH

C. Indications for Use:

The P.F.C. Sigma Porous Modular Keel Tibial Tray is indicated for use in total knee replacements for patients suffering from severe pain and disability due to permanent structural damage in the knee joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, or pseudogout. This damage may also be the result of trauma or failed prior surgical intervention.

In accordance with Federal (USA) requirements, the P.F.C. Sigma Knee Modular Keel Tibial Tray is indicated for use only with PMMA bone cement.

510(k) Summary (Continued)
P.F.C. Sigma Porous Modular Keel Tibial Tray

D. Device Description:

The P.F.C. Sigma Porous Modular Keel Tibial Tray is manufactured from titanium alloy (Ti-6Al-4V). The distal surface, including approximately one-third of the stem and P.F.C. Sigma Porous Modular Keel Tibial Tray portions, is coated with commercially pure titanium porous coating to enhance cement fixation. If additional fixation is required, the tibial tray is designed with four screw holes that accept bone screws.

The distal tip of the P.F.C. Sigma Porous Modular Keel Tibial Tray is manufactured with a UHMWPE plug. When a long stem device is required the UHMWPE plug is removed to allow the tibial tray to accept attachment of a metallic extension.

The P.F.C. Sigma Porous Modular Keel Tibial Tray is designed for use with both P.F.C. Modular and P.F.C. Sigma tibial inserts, including curved posterior lipped and stabilized.

E. Substantial Equivalence:

The P.F.C. Sigma Porous Modular Keel Tibial Tray is substantially equivalent in terms of intended use, materials, design, sterilization method, and packaging to the P.F.C. Modular Tibial Tray –Porous (K892394 and K961685), P.F.C. Modular Plus Tibial Tray (K923807 and K961685), AMK Total Knee (K864671) and CRX Tibial Tray (K961379).

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ASTM F-1580, ASTM F620 and ASTM F1044.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Janet G. Johnson, RAC
Senior Regulatory Associate
DePuy Orthopaedic, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K991106
P.F.C. Sigma Porous Modular Keel Tibial Tray
Regulatory Class: II
Product Code: JHW
Dated: March 30, 1999
Received: April 1, 1999

Dear Ms. Johnson:

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.

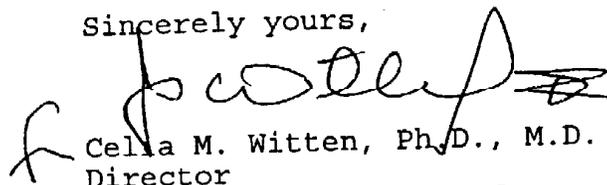
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Cella 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) K991106
Device Name P.F.C. Sigma Porous Modular Keel Tibial Tray

Indications for Use

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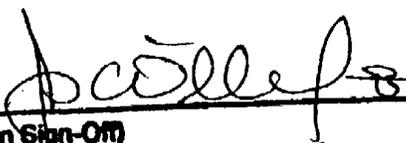
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR §801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991106