JAN 28 1999

K984158

510(k) Summary of Safety and Effectiveness

P.F.C.® Modular Plus Offset Tibial Tray

Manufacturer: Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

A. *Contact Person:*

Arlene C. Saull, RAC
Sr. Submissions Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
(219) 372-7276

B. *Device Information:*

Proprietary Name:	P.F.C.® Modular Plus Offset Tibial Tray
Common Name:	Total Knee Prosthesis Tibial Tray Component
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.® Modular Total Knee System is indicated for use in a total knee replacement 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.

The P.F.C.® Modular Plus Offset Tibial Tray is indicated for use with polymethylmethacrylate (PMMA) bone cement.

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D. *Device Description:*

The P.F.C.® Modular Plus Offset Tibial Tray is part of a modular system for use in total knee replacement. The subject device is a titanium tibial tray component, which is designed to accept snap-in tibial inserts in a range of thicknesses and a variety of surface topographies.

The P.F.C.® Modular Plus Offset Tibial Tray and its parent device, the P.F.C.® Modular Plus Tibial Tray (K923807) have the same keel geometry and adjusted cement pockets that accommodate four screw holes for optional wedge attachment.

The P.F.C.® Modular Plus Offset Tibial Tray has been designed with a proximal baseplate offset from the central stem to accommodate patients whose anatomic canal is not centered within the tibia.

E. *Substantial Equivalence:*

The P.F.C. ® Modular Plus Offset Tibial Tray is similar in performance, intended use, materials, design, performance characteristics, packaging, and sterilization method to the P.F.C.® Modular Tibial Tray (K884796 and K892394), the P.F.C.® Modular Plus Tibial Tray (K923807), and the Zimmer NexGen® LCCK Knee System (K960279).

The determination of substantial equivalence for this device is based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ASTM F136 and the FDA *"Draft Guidance for the Preparation of Premarket Notifications {510(k)s} for Cemented, Semi-Constrained Total Knee Prostheses."*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 1999

Arlene C. Saull, RAC
Senior Submissions Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K984158
P.F.C® Modular Plus Offset Tibial Tray
Regulatory Class: II
Product Code: JWH
Dated: November 18, 1998
Received: November 19, 1998

Dear Ms. Saull:

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) K984158

Device Name **P.F.C.® Modular Plus Offset Tibial Tray**

Indications For Use

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(Please do not write below this line - continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984158

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

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