Johnson & Johnson
PROFESSIONAL, INC.

510(k) Summary

K971189

JUL 17 1997

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

Contact Person: John D. Ferros
Phone:(508) 880-8287
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Name of Device

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis has been placed in Class II by the FDA under 21 CFR 888.3560. This falls under the Orthopaedics panel/87.

Common Name: Semi-constrained total knee prosthesis.

Trade Name/Proprietary Name: **P.F.C.® Σ Sigma Knee System (Size 1.5)**

Performance Standards: No performance standards have been developed as yet for this device.

Predicate Device

P.F.C.® Σ Sigma Knee System

Description of Device

The P.F.C.® Σ Sigma Knee System (Size 1.5) consists of:

1. Femoral components with an asymmetric trochlear groove;
2. Tibial inserts or All-Polyethylene Tibiae;
3. Femoral augmentation pieces;
4. Tibial Wedges.

The device is a prosthetic device intended to replace the natural knee joint. The device is constructed of UHMWPE, Titanium and Co-Cr-Mo alloy.

Intended Use

The P.F.C.® Σ Sigma Knee System (Size 1.5) is indicated for use only with bone cement (PMMA) for patients suffering from severe pain and disability due to permanent structural damage resulting 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.

Technological Characteristics Compared to Predicate Device

All the components of the P.F.C.® Σ Sigma Knee System (Size 1.5) are identical to the components of the previously cleared P.F.C.® Σ Sigma Knee System, except they are designed in a smaller size. All materials used in the P.F.C.® Σ Sigma Knee System (Size 1.5) are also identical to the P.F.C.® Σ Sigma Knee System.

Performance Tests

The following tests were conducted for a determination of substantial equivalence:
Constraint Testing
Contact Areas/Contact Stress between all Interfacing Components
Surface Characteristics of Articulating Surfaces
Tibial Insert/Tibial Tray Interlock Testing
Lateral Stability of Patellofemoral Joint

All testing concluded the device performed as well or better that the predicate device.

325 PARAMOUNT DRIVE, RAYNHAM, MASSACHUSETTS 02767-0350 (508) 880-8100

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John D. Ferros
Senior Regulatory Affairs Specialist
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

JUL 17 1997

Re: K971189
P.F.C. Σ Sigma Knee System (Size 1.5)
Regulatory Class: II
Product Code: JWH
Dated: June 30, 1997
Received: July 2, 1997

Dear Mr. Ferros:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,

for 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): K971189

Device Name: **P.F.C.® Σ Sigma Knee System (Size 1.5)**

Indications for Use:

The P.F.C.® Σ Sigma Knee System (Size 1.5) is indicated for use only with bone cement (PMMA) for patients suffering from severe pain and disability due to permanent structural damage resulting 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.

(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 K971189

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)