K980801

Summary of Safety and Effectiveness Data for the J-FX Bipolar Head

MAY 29 1998

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

Contact Person

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Name of Device

Proprietary Name:	J-FX™ Bipolar Head
Common Name:	Metal/Polymer Femoral Head Endoprothesis (Bipolar Cup)
Classification Name:	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
Regulatory Class:	Class II by 21 CFR 888.3390
Product Code:	KWY
Owner/Operator No.:	9001269

Device Classification

This device has been placed in Class II for Hip joint femoral (hemi-hip) metal /polymer cemented c uncemented prosthesis per 21 CFR § 888.3390.

Statement of Substantial Equivalence

The J-FX Bipolar Head is substantially equivalent to the P.F.C.® Bipolar Hip System cleared for marketing under premarket notifications K945793 (April 10, 1995)/ K931655 (June 9, 1994). The devices are identical in material, with the outer shell composed of cobalt-chrome alloy and the inner liner composed of UHMWPE. Both devices are identical in function (indicated use).

Indications for Use

The J-FX Bipolar Head is indicated for use in partial hip replacement procedures for patients suffering severe pain and disability due to:

- femoral fracture
- avascular necrosis of the femoral head
- osteoarthritis
- other abnormalities:
  - where the major pathology affects the femoral head,
  - where the acetabular cavity is normal and not deformed or weakened, and
  - where acetabular replacement is not required or desirable.

Physical Description

The J-FX Bipolar Head is composed of an Co-Cr-Mo alloy shell (ASTM F75) and a ultra-high-molecular weight polyethylene (UHMWPE) liner. The liner is a three piece design consisting of a bearing insert, inner retaining ring and an outer locking ring. The bearing insert and inner retaining ring provide the bearing surface for the femoral hip head while the locking ring holds the liner assembly in place in the shell.

The outer diameter of the metal shell varies in size from 38 through 58 mm in 1 mm increments for use with the 22.225 mm UHMWPE liner. For the 28 mm UHMWPE liner, the size range for the metal shell is 42 through 58 mm in 1 mm increments. A 60 mm metal shell is also available for use with both the 22.225 mm and 28 mm UHMWPE liner.

Five sizes of polyethylene liners are available for the 22.225 mm J-FX Bilpolar head and four sizes for the 28 mm J-FX Bipolar head. With this availability of liner sizes, the mating of the full range of outer shell sizes are met. The polyethylene thickness ranges from 4.1 to 12.1 mm for the 22.225 mm head and 3.7 to 9.2 mm for the 28 mm head.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1998

Ms. Mary E. Gray
Associate Regulatory Affairs Specialist
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K980801
Trade Name: J-FX™ Bipolar Head
Regulatory Class: II
Product Code: KWY
Dated: February 25, 1998
Received: March 2, 1998

Dear Ms. Gray:

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.

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

SECTION II

Indications for Use

Indications for Use

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- femoral fracture
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  - where the acetabular cavity is normal and not deformed or weakened, and
  - where acetabular replacement is not required or desirable.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division [illegible] estorative Devices
510(k) Number K980801