K02 3743

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**Smith & Nephew, Inc.**
**Summary of Safety and Effectiveness :Global Bipolar System**

**Contact Person and Address**
Janet Akil
Director, Clinical and Regulatory Affairs
Smith & Nephew, Inc., Orthopaedics Division
1450 East Brooks Road
Memphis, TN 38116
(901) 399-5153

**Date of Summary:** November 6, 2002

JAN 2 3 2003

**Name of Device: Global Bipolar System**
**Common Name:** Bipolar System
**Device Classification Name**
21 CFR 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis

**Substantial Equivalence Information**
The **Global Bipolar System** is substantially equivalent to the following: Smith & Nephew Bipolar System, Centrax Bipolar System; Multipolar Bipolar System; Self-Centering Bipolar System; and the Ringloc Bipolar System.

**Device Description**
The **Global Bipolar System** consists of a bipolar shell, bipolar liner, full lock ring liner, and a metal retaining ring. The system is to be used with existing femoral heads distributed by Smith & Nephew.

**Indications for Use**
The Global Bipolar System is indicated for the following:

1. Non-inflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
2. rheumatoid arthritis;
3. arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
4. revision procedures where other treatment or devices have failed; and
5. treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

**Technological & Performance Characteristics**:
The **Global Bipolar System** is similar to currently marketed bipolar systems. The components share the same intended use, material, and design features of one or more of the above mentioned predicates. A review of the mechanical test data indicated that the **Global Bipolar System** is equivalent to devices currently on the market and are capable of withstanding expected *in vivo* loading without failure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2003

Ms. Janet J. Akil
Director, Regulatory Affairs
Orthopaedic Division
Smith & Nephew, Inc.
1450 Brooks Road.
Memphis, Tennessee 38116

Re: K023743
Trade Name: Global Bipolar System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY
Dated: November 6, 2002
Received: November 7, 2002

Dear Ms. Akil:

We have reviewed your Section 510(k) premarket 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) 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

for 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

K023743

# Global Bipolar System
# Indications Statement

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Concurrence of CDRH, Office of Device Evaluation

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

for Mark N Milhous

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

510(k) Number K023743