K030603
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510(K) SUMMARY

SMITH & NEPHEW PROFIX TOTAL KNEE SYSTEM

MAY 22 2003

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6707
CONTACT PERSON:	Gino J. Rouss
DATE SUMMARY PREPARED:	February 26, 2003
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Profix Total Knee System
COMMON OR USUAL NAME:	Total Knee Prosthesis
CLASSIFICATION NAME:	Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
DEVICE CLASS:	Class II
DEVICE PRODUCT CODE:	MBH
PANEL CODE:	Orthopedics/87

DEVICE INFORMATION:

A. **INTENDED USE:**
The Profix Total Knee System is indicated for:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity levels are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The posterior stabilized knee system is designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The Profix Total knee system includes porous coated devices which are indicated for use without bone cement, and are single use devices.

B. **DEVICE DESCRIPTION:**
The overall design, components, and materials of the Profix Total Knee System are substantially equivalent to the existing components of the Profix Total Knee System cleared under previous premarket notifications. The main difference between the subject components of the Profix Total Knee System, and the currently marketed components is the intended use of the system without bone cement.

C. **SUBSTANTIAL EQUIVALENCE INFORMATION:**
Smith & Nephew, Inc. concludes that the Profix Total Knee System is substantially equivalent to the currently marketed knee prosthesis filed with the following premarket notifications: Profix Total Knee System (K933958), Profix Posterior-Stabilized Knee System (K954909), Profix Knee Posterior-Stabilized Plus Tibial Insert (K963255), Tricon Knee System (K884824), and Freeman-Samuelson Mark II Press-Fit Total Knee Replacement (K853730)

D. **SUMMARY OF TECHNOLOGICAL COMPARISON:**
The intended use, designs, and materials of the Profix Total Knee System are substantially equivalent to the predicate components found in the original Profix System submissions previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2003

Mr. Gino J. Rouss
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthpaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K030623
Trade/Device Name: Profix Total Knee System
Regulation Numbers: 21 CFR 888.3565
Regulation Names: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Codes: MBH
Dated: February 26, 2003
Received: February 27, 2003

Dear Mr. Rouss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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

510(k) Number (if known): K030623

Device Name: **Smith & Nephew Profix Total Knee System**

Indications For Use:

The Profix Total Knee System is indicated for:

1. Rheumatoid arthritis.

2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity levels are compatible with an adequate long-term result.

3. Failed osteotomies, unicompartmental replacement, or total knee replacement.

4. The posterior stabilized knee system is designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The Profix Total Knee System includes porous coated devices which are indicated for use without bone cement, and are single use devices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Mark N Milleson

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

510(k) Number K030623