K041106

JUL 01 2004

510(K) SUMMARY

SMITH & NEPHEW REVISION KNEE SYSTEM

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6566
CONTACT PERSON:	Kim P. Kelly
DATE SUMMARY PREPARED:	April 27, 2004
TRADE OR PROPRIETARY DEVICE NAME:	Revision Knee System
COMMON OR USUAL NAME:	Femoral Components, Wedges, and Wedge Screws
CLASSIFICATION NAME:	Knee Joint Patellofemorotibial Metal/Polymer/Metal Semi-Constrained Cemented Prosthesis
DEVICE CLASS:	Class II
PANEL CODE:	Orthopedics/87

DEVICE INFORMATION:

A. **INTENDED USE:**

The Revision Knee System Components are indicated for rheumatoid arthritis; post-traumatic arthritis; osteoarthritis; degenerative arthritis; and failed osteotomies, hemiarthroplasties; unicompartmental replacement; or total knee arthroplasties. The components are designed for use in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent. The Revision Knee Components are for single use only and are intended for implantation with bone cement.

These indications are the same as currently used for the Genesis II Constrained Knee System cleared via K962137.

B. **DEVICE DESCRIPTION:**

The Revision Femoral Knee Components are manufactured from Oxinium. Wedges and screws are also included in the Revision Knee System. The designs of the devices are based upon existing components of the Genesis II Total Knee System.

C. **SUBSTANTIAL EQUIVALENCE INFORMATION:**

The substantial equivalence of the Revision Knee System Components is substantiated by its similarities in design features, overall indications, and material composition to existing components contained within the Genesis II Total Knee System manufactured and distributed by Smith & Nephew, Inc.

D. **SUMMARY OF TECHNOLOGICAL COMPARISON:**

The intended use, designs, and materials of the Revision Knee System are substantially equivalent to the predicate components found in the previously cleared Genesis II System submissions. Design Control Activities have been completed and the results indicate that the subject devices meet the requirements of the applicable FDA guidance documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 1 2004

Ms. Kim Kelly
Project Manager, Regulatory and Clinical Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K041106
Trade/Device Name: Smith & Nephew Revision Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: May 28, 2004
Received: June 1, 2004

Dear Ms. Kelly:

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,

Miriam C. Provost

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):

Device Name: Revision Knee System

Indications For Use:

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(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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041106