K100197

510(K) Summary

Smith & Nephew Genesis Unicondylar UHMWPe Articular Inserts

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6707 FEB 19 2010
CONTACT PERSON:	Gino J. Rouss
DATE SUMMARY PREPARED:	January 20, 2010
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Genesis Unicondylar UHMWPe Articular Inserts
COMMON OR USUAL NAME:	Knee Prosthesis
CLASSIFICATION NAME:	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis, 21 CFR 888.3520
DEVICE CLASS:	Class II
PANEL CODE:	HSX Orthopedics Panel/87

A. Intended Use

The Genesis Unicondylar UHMWPe Articular Inserts are indicated for restoring either compartment of a knee that has been affected by the following:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques.

The implants are single use only and are designed to be used in combination with existing Genesis Unicondylar baseplates that are intended for implantation with bone cement.

B. Device Description

New unicondylar UHMWPe articular inserts have been designed and developed by Smith & Nephew Orthopaedics. The subject devices were designed to be used with existing Genesis Unicondylar baseplates (K912735) and are intended to replace either the medial or lateral tibial compartment of the knee. The overall design of the articular inserts is based on the existing Genesis Unicondylar inserts cleared via 510(k) Premarket Notification K912735.

C. Substantial Equivalence

The Smith & Nephew Genesis Unicondylar UHMWPe Articular Inserts are similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew Genesis Unicompartmental Articular Knee Inserts (K912735)
- Smith & Nephew Journey Unicondylar Articular Knee Inserts (K061011)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Mr. Gino J. Rouss, MS
Manager, Regulatory Affairs
1450 East Brooks Road
Memphis, Tennessee 38116

FEB 19 2010

Re: K100197
Trade Name: Smith & Nephew Genesis Unicondylar UHMWPe Articular Inserts
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSX
Dated: January 20, 2010
Received: January 22, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Genesis Unicondylar UHMWPe Articular Inserts

INDICATIONS FOR USE:

The Genesis Unicondylar UHMWPe Articular Inserts are indicated for restoring either compartment of a knee that has been affected by the following:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100197