MAY 18 2012

K120698

Contact Person and Address:
Xiang Zhang
Director, Regulatory Affairs
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116
T (901) 399-6929

Date of Summary: February 28; 2012

Name of Device: Genesis II PS Non-modular Femoral Components; Genesis II CR Non-modular with cement pocket Femoral Components; Genesis II Select Femoral Components; Genesis II ECO Instruments
Common Name: Knee Prosthesis
Device Classification Name and Reference:
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, 21 CFR 888.3560
Device Class: Class II.
Panel Code: Orthopaedics/87 JWH
Predicate Device: Genesis II Total Knee System, K951987

Device Description
Genesis II PS Non-modular and CR Non-modular with cement pocket femoral components are line extension of the Genesis II Total Knee System. It provides a non-modular option of the PS knee which is similar to the non-modular CR knee in design concept. It is available from size 1-8 and in left and right configuration. The Non-modular PS/CR femoral components are available with or without the feature of cement pocket. The material is cobalt chromium alloy (ASTM F75-07). The femoral component is a single use device and supplied sterile (Gamma sterilization). The Genesis II PS Non-modular and CR Non-modular with cement pocket femoral components can be implanted using the standard Genesis II Instrumentation or the *Genesis II ECO* Instrumentation.

Intended Use
The Genesis II PS Non-modular and CR Non-modular with cement pocket Femoral Components are indicated for:
1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are 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 Genesis II PS Non-modular and CR Non-modular with cement pocket Femoral Components are indicated for use only with cement and are single use devices.

Performance Data
Design verification has been performed based on requirements outlined in FDA's *Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses*, dated April 1993. Technical report and justifications provided in the submission demonstrated that the Genesis II PS Non-modular and CR Non-modular with cement pocket Femoral Components met performance requirements and are as safe and effective as the predicate devices.

Clinical data was not needed to support the safety and effectiveness of the subject devices.

Substantial Equivalence Information

The Smith & Nephew Genesis II PS Non-modular and CR Non-modular with cement pocket Femoral Components are similar to the following commercially available devices regarding indications and technological characteristics:

- Smith & Nephew Genesis II Total Knee System (K951987)

Conclusion

This Special 510(k) Premarket Notification is being submitted for new Genesis II PS Non-modular and CR Non-modular with cement pocket Femoral Components that have been designed and developed by Smith & Nephew Inc. Given that the new devices have met all performance requirements and share the same design features, indications, and materials as the predicates, the devices can be considered substantially equivalent to femoral components currently marketed under K951987.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 18 2012

Smith & Nephew, Inc.
% Mr. Xiang Zhang,
Director of Regulatory Affairs
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K120698
Trade/Device Name: Smith & Nephew Genesis II PS Non-modular and CR Non-modular with cement pocket Femoral Components
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: April 19, 2012
Received: April 20, 2012

Dear Mr. Zhang:

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): K120698

Device Name: Smith & Nephew Genesis II PS Non-modular and CR Non-modular with cement pocket Femoral Components

INDICATIONS FOR USE:

The Genesis II PS Non-modular and CR Non-modular with cement pocket Femoral Components are indicated for:

1. Rheumatoid arthritis.
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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 K120698