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Smith & Nephew, Inc.
Summary of Safety and Effectiveness
Crosslinked Polyethylene Articular Inserts

SEP 19 2007

Contact Person and Address
Rishi Sinha
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Smith & Nephew, Inc.
Orthopaedic Reconstruction
1450 Brooks Road
Memphis, TN 38116
(901)399-6054

Date of Summary: 04/12/2007

Name of Device: Crosslinked Polyethylene Articular Inserts
Common Name: Articular Inserts

Device Description

The intended use, base material, and design specifications of the Smith & Nephew Crosslinked Polyethylene articular inserts for the Journey and Genesis II knee systems are the same as subject identical components fabricated from conventional non-Crosslinked Ultra High Molecular Weight Polyethylene. The devices subject to this premarket notification have been Crosslinked by a proprietary process. As a result, the polymer is highly crosslinked with increased wear performance properties over traditional UHMWPE.

Device Classification

21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis – Class II

21 CFR 888.3565 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained uncemented prosthesis – Class II

Indications for Use

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis for use in primary and revision surgeries. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. Constrained Knee Systems are designed for use in patients in primary and revision surgeries, where the posterior cruciate ligament and one or both of the colateral ligaments (i.e. medial cruciate ligament and one or both of the collateral ligaments) are absent or inadequate. The indications for each device system are identical to the indications for each cleared predicate knee system.

Substantial Equivalence Information

The overall design and function of the Crosslinked components have not been changed over that of their identical counterparts manufactured from conventional UHMWPE listed in the table below:

DESCRIPTION	510(K)	CLEARANCE DATE
Genesis II Knee System (cemented use)	K951987	8/22/95
Genesis II Knee System (uncemented use)	K030612	5/27/03
Genesis II Constrained Knee System	K962137	8/2/96
Genesis II High Flex PS Articular Inserts	K032295	8/21/03
Genesis II Deep Flex CR Articular Inserts	K041825	3/11/05
High Performance Knee (Journey BCS)	K042515	3/14/05

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Mr. Rishi Sinha
Regulatory Affairs Specialist
1450 E. Brooks Road
Memphis, Tennessee 38116

SEP 19 2007

Re: K071071
Trade/Device Name: Crosslinked Polyethylene Articular Inserts
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: August 24, 2007
Received: August 28, 2007

Dear Mr. Sinha:

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K071071

Device Name: Crosslinked Polyethylene Articular Inserts

Indications for Use:

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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 General, Restorative, and Neurological Devices

510(k) Number K071071