K041525

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Smith & Nephew, Inc.
Summary of Safety and Effectiveness
Genesis II Deep Flexion Cruciate Retaining Articular Insert

Contact Person and Address
Kim Kelly
Project Manager, Clinical/Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116
(901) 399-6566

Date of Summary: July 6, 2004

MAR 11 2005

Name of Device: Genesis II Deep Flexion Cruciate Retaining Articular Insert
Common Name: Articular insert

Device Description
The Genesis II Deep Flexion Cruciate Retaining Articular Inserts are UHMWPE tibial components which provide the ability for greater flexion to those patients who have the anatomical capability to allow a greater flexion range. The insert is used with existing cemented femoral, tibial tray, and patellar components of the Genesis II Total Knee System cleared via K951987 and K953274 or with the system's porous, uncemented femoral and tibial tray components cleared in K030612.

Device Classification

Identification of Device	Product Code	Classification Name	Code	Predicate 510(k)
Genesis II Deep Flexion C/R Insert for use with Genesis II Total Knee System Components in cemented applications	JWH – Orthopaedics Panel/87	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis – Class II	21 CFR 888.3560	K951987 K953274
Genesis II Deep Flexion C/R Insert for use with Genesis II Total Knee System Components in uncemented applications	MBH – Orthopaedics Panel/87	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis – Class II	21 CFR 888.3565	K030612

Mechanical and Clinical Data
A review of the mechanical test data indicated that the Genesis II Deep Flexion Cruciate Retaining Articular Insert is equivalent to devices currently used clinically and is capable of withstanding expected *in vivo* loading without failure.

Indications for Use

Identification of Device	Indications for Use	Predicate 510(k)
Genesis II Deep Flexion C/R Insert for use with Genesis II Total Knee System Components in cemented applications	The Genesis II Deep Flexion Cruciate Retaining Articular Insert is intended to be used in conjunction with the components of the Genesis II Total Knee System. The Genesis II Total Knee System is indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. 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. The Genesis II Deep Flexion Cruciate Retaining Articular Insert is used with existing cemented femoral, tibial tray, and patellar components of the Genesis II Total Knee System cleared via K951987 and K953274. The Genesis II Deep Flexion Cruciate Retaining Articular Insert is for single use only.	K951987 K953274
Genesis II Deep Flexion C/R Insert for use with Genesis II Total Knee System Components in uncemented applications	The Genesis II Deep Flexion Cruciate Retaining Articular Insert is intended to be used in conjunction with the components of the Genesis II Total Knee System. The Genesis II Total Knee System is indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. 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. The Genesis II Deep Flexion Cruciate Retaining Articular Insert is used with existing cemented patellar and uncemented porous tibial trays and femoral components of the Genesis II Total Knee System cleared via K030612. The Genesis II Deep Flexion Cruciate Retaining Articular Insert is for single use only.	K030612

Substantial Equivalence Information

The substantial equivalence of the Genesis II Deep Flexion Cruciate Retaining Articular Insert is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – Smith & Nephew's Genesis II Total Knee System (K951987, K953274, and K030612) and the Genesis II P/S High Flexion Articular Insert (K032295).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jason Sells
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

MAR 1 1 2005

Re: K041825
Trade/Device Name: Genesis II Deep Flexion Cruciate Retaining Articular Insert
Regulation Number: 21 CFR 888.3560, 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis; and Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: JWH, MBH
Dated: February 8, 2005
Received: February 9, 2005

Dear Mr. Sells:

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.

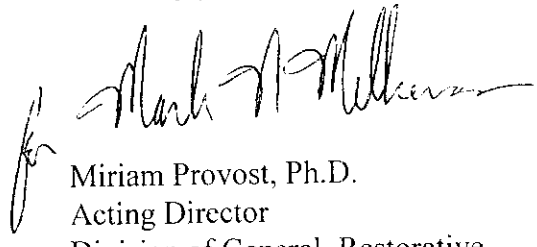
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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/industry/support/index.html.

Sincerely yours,



Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Genesis II Deep Flexion Cruciate Retaining Articular Insert

Indications for Use:

The Genesis II Deep Flexion Cruciate Retaining Articular Insert is intended to be used in conjunction with the components of the Genesis II Total Knee System.

The Genesis II Total Knee System is indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. 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.

The Genesis II Deep Flexion Cruciate Retaining Articular Insert is used with existing cemented femoral, tibial tray, and patellar components of the Genesis II Total Knee System cleared via K951987 and K953274. The Genesis II Deep Flexion Cruciate Retaining Articular Insert is for single use only.

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)

for Mark N Melkerson

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

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Indications for Use

510(k) Number (if known):

Device Name: Genesis II Deep Flexion Cruciate Retaining Articular Insert

Indications for Use:

The Genesis II Deep Flexion Cruciate Retaining Articular Insert is intended to be used in conjunction with the components of the Genesis II Total Knee System.

The Genesis II Total Knee System is indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. 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.

The Genesis II Deep Flexion Cruciate Retaining Articular Insert is used with existing cemented patellar and uncemented porous tibial trays and femoral components of the Genesis II Total Knee System cleared via K030612. The Genesis II Deep Flexion Cruciate Retaining Articular Insert is for single use only.

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)

for Mark N Milhous

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

510(k) Number K041825