K121393

Summary of Safety and Effectiveness
Total Knee System Instruments
Smith & Nephew, Inc.

Contact Person and Address
Gino Rouss, MS
Group Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
7135 Goodlett Farms Parkway
Memphis, Tennessee 38016
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Date of Summary: May 8, 2011

AUG 7 2012

Name of Device: Total Knee System Instruments
Common Name: Orthopaedic Surgical Instrumentation
Device Classification Name and Reference:

CFR Number	Description	Classification
888.3510	Knee joint femorotibial metal/polymer constrained cemented prosthesis	II
888.3520	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	II
888.3530	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	II
888.3540	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	II
888.3560	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis	II
888.3565	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis	II

Device Class: Class II
Panel Code: Orthopaedics/87

Predicate Devices:

Smith & Nephew Inc. Cemented Total Knee Systems

Description	510(k)	Clearance Date
GENESIS II TOTAL KNEE SYSTEM	K951987	8/22/1995
GENESIS POROUS TIBIAL TRAYS & REVISION KNEE SYSTEM	K953274	2/5/1996
PROFIX POSTERIOR STABILIZED KNEE SYSTEM	K954909	1/31/1996
GENESIS II POROUS PLUS HA KNEE SYSTEM	K032683	10/15/2003
GENESIS II DEEP FLEXION CRUCIATE RETAINING ARTICULAR INSERT	K041825	3/11/2005
HIGH PERFORMANCE KNEE	K042515	3/14/2005
PROFIX FLEX CRUCIATE RETAINING ARTICULAR INSERT	K051229	7/20/2005
JOURNEY CR KNEE SYSTEM	K101499	8/26/2010
GENESIS II ZIRCONIUM FEMORAL COMPONENT/PROFIX ZIRCONIUM FEMORAL COMPONENT	K962557	12/5/1996
GENESIS II POSTERIOR STABILIZED HIGH FLEXION INSERT	K032295	8/21/2003
PROFIX CONFOMRING PLUS TIBIAL INSERT	K946236	7/6/1995

Smith & Nephew Inc. Cementless Total Knee Systems

Description	510(k)	Clearance Date
GENESIS II POROUS PLUS HA KNEE SYSTEM	K032683	10/15/2003
PROFIX TOTAL KNEE SYSTEM	K030623	5/22/2003
GENESIS II TOTAL KNEE SYSTEM	K030612	5/27/2003
LEGION POROUS + HA TIBIAL BASEPLATES	K100897	5/13/2010
LEGION POROUS PRIMARY	K073325	12/20/2007
LEGION POROUS PLUS HA PRIMARY FEMORAL COMPONENTS	K091543	12/21/2009
PROFIX FLEX CRUCIATE RETAINING ARTICULAR INSERT	K051229	7/20/2005
GENESIS II POSTERIOR STABILIZED HIGH FLEXION INSERT	K032295	8/21/2003
GENESIS II DEEP FLEXION CRUCIATE RETAINING ARTICULAR INSERT	K041825	3/11/2005

Smith & Nephew Inc. Constrained Total Knee Systems

Description	510(k)	Clearance Date
GENESIS II CONSTRAINED KNEE SYSTEM	K962137	8/2/1996
REVISION KNEE SYSTEM	K043440	2/18/2005
LEGION COBALT CHROME REVISION KNEE SYSTEM	K060742	5/3/2006
CROSSLINKED POLYETHYLENE ARTICULAR INSERTS	K071071	9/19/2007
LEGION STEM WITH HOLES	K072531	12/6/2007
PROFIX PLUS TIBIAL INSERT, PROFIX PS PLUS TIBIAL INSERT, PROFIX P/S TIBIAL INSERT	K963255	1/2/1997
REVISION KNEE SYSTEM	K041106	7/1/2004

Smith & Nephew Inc. Hinged Total Knee System

Description	510(k)	Clearance Date
LEGION HINGE KNEE SYSTEM	K081111	7/23/2008

Device Description

Subject of this Traditional 510(k) Premarket Notification are the Smith & Nephew, Inc. Total Knee System Instruments. The subject devices are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Total Knee Systems and their cleared Indications for Use. Smith & Nephew Total Knee System Instruments can be organized into instrument families which are categorized as follows: Trials, Cutting Instruments and Cutting Guides; Cutting Blocks, Alignment and Sizing Instruments, Impactors and Handles, Clamps, Extraction, Torque, Instrument Guides, and Covers and Protectors.

Intended Use / Indications for Use

Smith & Nephew Total Knee Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Total Knee Systems and their cleared Indications for Use.

Indications for Cruciate Retaining Cemented Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.

Cruciate Retaining Cemented Knee components are indicated for use with cement and are single use devices.

Indications for Cruciate Retaining Cementless Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.

Cruciate Retaining Cementless Knee components are indicated for use without cement and are single use devices.

Indications for Posterior Stabilized Cemented Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

Posterior Stabilized Cemented Knee components are indicated for use with cement and are single use devices.

Indications for Posterior Stabilized Cementless Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

Posterior Stabilized Cementless Knee components are indicated for use without cement and are single use devices.

Indications for Constrained Total Knees

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Constrained knee systems are designed for use in patients 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 incompetent.

Constrained Total Knee components are indicated for use with cement and are single use devices.

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

Smith & Nephew, Inc.
% Mr. Gino Rouss
Group Manager, Regulatory Affairs
1450 E Brooks Road
Memphis, Tennessee 38116

AUG 7 2012

Re: K121393
Trade/Device Name: Smith & Nephew Inc. Total Knee System Instrumentation
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, HRY, HSX, KRO, KRQ, KRR, NPJ
Dated: May 8, 2012
Received: May 9, 2012

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.

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 Inc. Hinged Total Knee Systems

Indications for Use:
Smith & Nephew Hinge Total Knee Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Hinge Total Knee Systems and their cleared Indications for Use.

Indications for Hinged Total Knees

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.
5. Hinge knee systems are designed for use in patients 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.

Hinged Total Knee components are indicated for use with cement and are single use devices.

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 K121393

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Inc. Constrained Total Knee Systems

Indications for Use:
Smith & Nephew Constrained Total Knee Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Constrained Total Knee Systems and their cleared Indications for Use.

Indications for Constrained Total Knees

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Constrained knee systems are designed for use in patients 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 incompetent.

Constrained Total Knee components are indicated for use with cement and are single use devices.

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

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Division of Surgical, Orthopedic,
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510(k) Number K121393

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Inc. Posterior Stabilized Cementless Knee Systems

Indications for Use:
Smith & Nephew Posterior Stabilized Cementless Knee Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Posterior Stabilized Cementless Knee Systems and their cleared Indications for Use.

Indications for Posterior Stabilized Cementless Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

Posterior Stabilized Cementless Knee components are indicated for use without cement and are single use devices.

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

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121393

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Inc. Posterior Stabilized Cemented Knee Systems

Indications for Use:
Smith & Nephew Posterior Stabilized Cemented Knee Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Posterior Stabilized Cemented Knee Systems and their cleared Indications for Use.

Indications for Posterior Stabilized Cemented Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

Posterior Stabilized Cemented Knee components are indicated for use with cement and are single use devices.

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

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Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121393

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Inc. Cruciate Retaining Cementless Knee Systems

Indications for Use:
Smith & Nephew Cruciate Retaining Cementless Knee Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Cruciate Retaining Cementless Knee Systems and their cleared Indications for Use.

Indications for Cruciate Retaining Cementless Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.

Cruciate Retaining Cementless Knee components are indicated for use without cement and are single use devices.

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

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Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121393

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Inc. Cruciate Retaining Cemented Knee Systems

Indications for Use:
Smith & Nephew Cruciate Retaining Cemented Knee Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Cruciate Retaining Cemented Knee Systems and their cleared Indications for Use.

Indications for Cruciate Retaining Cemented Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.

Cruciate Retaining Cemented Knee components are indicated for use with cement and are single use devices.

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

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510(k) Number K121393