510 (k) **Summary of Safety and Effectiveness** K123159 (1/2)
Disposable Knee Instruments
Smith & Nephew, Inc.

Contact Person and Address
Martin Ostmann
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
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Memphis, TN 38116
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Date of Summary: May 3, 2013

MAY 0 3 2013

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

CFR Number	Description	Classification
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
Product Code: JWH, MBH

Predicate Devices:
Smith & Nephew Inc. Compatible Knee Systems

Description	510(k)	Clearance Date
LEGION PRIMARY KNEE SYSTEM	K093746	4/14/10
GENESIS II TOTAL KNEE SYSTEM	K951987	8/22/1995
GENESIS II P/S HIGH FLEXION KNEE INSERT	K032295	8/21/03
GENESIS II DEEP FLEXION C/R ARTICULAR INSERT	K041825	3/11/05
TOTAL KNEE SYSTEM INSTRUMENTATION	K121393	8/7/12

Device Description

Subject of this Traditional 510(k) Premarket Notification are the Smith & Nephew, Inc. Disposable Knee Instruments. The subject devices are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew, Inc. Genesis II and Legions total knee systems and their cleared indications for use for Total Knee Replacement.

Intended Use / Indications for Use

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

Substantial Equivalence Information

The Disposable Knee Instruments are considered substantially equivalent to previously cleared device specific instruments in that both subject and predicate instruments:

- Have demonstrated biocompatibility through ISO 10993 testing or through use of previously cleared predicate raw materials;
- Have similar or equivalent dimensions;
- Share identical surgical procedures;
- Utilize the same sterilization procedures; and
- Have similar nature of body contact

The Smith and Nephew Disposable Knee Instruments are similar in design and function to the existing Smith and Nephew Total Knee Instrumentation cleared via K121393.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 3, 2013

Smith & Nephew, Incorporated
% Mr. Martin Ostmann
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K123159
Trade/Device Name: Disposable Knee Instruments
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: April 12, 2013
Received: April 15, 2013

Dear Mr. Ostmann:

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 contact 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. 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,

Erin D. Keith

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

Enclosure

Indications for Use

510(k) Number (if known): K123159

Device Name: Disposable Knee Instruments
Indications for Use:

Smith & Nephew Disposable Knee Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew, Inc. Genesis II and Legions total knee systems and their cleared indications for use for Total Knee Replacement.

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

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices