K113038(1/3)

JAN - 5 2012

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

Contact Person and Address
Gino J. Rouss, MS
Group Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
7135 Goodlett Farms Parkway
Memphis, Tennessee 38016
T (901) 399-6707

Date of Summary: November 29, 2011

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

21 CFR 888.3520 – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
21 CFR 888.3540 – Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis

Device Class: Class II
Panel Code: Orthopaedics/87
Predicate Devices:

Journey Unicondylar Femoral Implant (K073175)
Unicondylar Femoral Component (K030301)
Competitor Deuce (Journey) Femoral Component – Sizes 1-8, Oxinium and CoCr (K061569)
Competitor (Journey) PFJ Patello-Femoral Knee Implant (Oxinium) (K051086)
Genesis Unicompartmental Knee System (K912735)
Journey Unicondylar Tibial Baseplastes (K102069)
Competitor Unicondylar Knee Tibial Baseplate (K061011)
Competitor Unicondylar All-Poly Tibial Baseplate (K061779)

Device Description

Subject of this Traditional 510(k) Premarket Notification are manual instruments associated with the Smith & Nephew Unicompartmental and Bicompartmental Knee Systems. The subject devices are accessory devices and are intended to be used to assist in the implantation of the Unicompartmental and Bicompartmental Knee Systems designed and manufactured by Smith & Nephew. The Smith & Nephew Unicompartmental and Bicompartmental Knee System Instruments can be separated into instrument families which are categorized as follows: Trials, Cutting Instruments and Cutting Guides; Cutting Blocks, Alignment Instruments, Impactors and Handles; and Speed Pins and Adaptors.

K113038 (2/3)

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

Indications for Use

Unicompartmental Knee Systems
Smith and Nephew Unicondylar Knee Systems are indicated for restoring either compartment of a knee that has been affected by the following:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques

Bicompartmental Knee Systems
Smith and Nephew Bicompartmental Knee Systems are intended to be used for those patients whereby conditions exist that cannot be solely addressed by a device that treats a single compartment (i.e. unicondylar or patellofemoral prosthesis) of the knee.

Indications include:

- Post-traumatic arthritis;
- Degenerative arthiritis; and
- Failed osteotomies, hemi-arthroplasties; and unicompartmental replacement

These indications will be used for Smith and Nephew Bicompartmental Knee Systems, whereby the medial condyle and patellofemoral regions have been affected by one or more of these conditions.

Patello-Femoral Joint Knee Systems
The Smith and Nephew Patello-Femoral Joint Knee Systems are indicated for replacement of the femoral side of the patello-femoral joint. They are intended to be used in patellofemoral arthoplasty in patients with:

- Degenerative arthritis in the distal femur and patella.
- A history of patellar dislocation or patellar fracture.
- Failed previous surgery (arthroplasty, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

Substantial Equivalence Information

The device specific instruments associated with the implant devices with which they are used are considered substantially equivalent to previously cleared device specific instruments in that both subject and predicate instruments:

- Share the same raw materials;
- Are manufactured though the same processes;
- Utilize the same sterilization procedures; and
- Have similar nature of body contact

The Smith and Nephew Unicompartmental and Bicompartmental Knee System Instruments are similar in design and function to competing unicompartmental and bicompartmental surgical instrumentation currently on the market.

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

JAN - 5 2012

Smith and Nephew, Inc.
% Gino J. Rouss, MS
1450 Brooks Road
Memphis, Tennessee 38116

Re: K113038
Trade/Device Name: Unicompartmental and Bicompartmental Knee System Instruments
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX, KRR, NPJ
Dated: October 10, 2011
Received: October 12, 2011

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. 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,

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

Enclosure

K113038 (1/3)

Indications for Use

510(k) Number (if known): K113038

Device Name: Smith and Nephew, Inc. Unicondylar Knee Systems

Indications for Use:

Smith and Nephew Unicondylar Knee Systems are indicated for restoring either compartment of a knee that has been affected by the following:

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Correction of functional deformity;
3. Revision procedures where other treatments or devices have failed; and
4. Treatment of fractures that are unmanageable using other techniques

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113038

Indications for Use

510(k) Number (if known): K113038

Device Name: Smith and Nephew, Inc. Bicompartmental Knee Systems

Indications for Use:

Smith and Nephew Bicompartmental Knee Systems are intended to be used for those patients whereby conditions exist that cannot be solely addressed by a device that treats a single compartment (i.e. unicondylar or patellofemoral prosthesis) of the knee.

Indications include:

- Post-traumatic arthritis;
- Degenerative arthiritis; and
- Failed osteotomies, hemiarthroplasties; and unicompartmental replacement

These indications will be used for Smith and Nephew Bicompartmental Knee Systems, whereby the medial condyle and patellofemoral regions have been affected by one or more of these conditions.

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 K113038

Indications for Use

510(k) Number (if known): K113038

Device Name: Smith and Nephew, Inc. Patellofemoral Joint Knee Systems

Indications for Use:

The Smith and Nephew Patello-Femoral Joint Knee Systems are indicated for replacement of the femoral side of the patello-femoral joint. They are intended to be used in patellofemoral arthoplasty in patients with:

1. Degenerative arthritis in the distal femur and patella.
2. A history of patellar dislocation or patellar fracture.
3. Failed previous surgery (arthroplasty, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113038