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510(k) Summary of Safety and Effectiveness

Legion Narrow Oxinium CR and PS Femoral Components and Device Specific Instruments

Submitted By:

Smith & Nephew, Inc.
Orthopaedics
1450 Brooks Road
Memphis, TN 38116

Date:

October 3, 2011

Contact Person:

David Henley, Regulatory Affairs Project Manager
Tel: (901) 399-6487 Fax: (901) 566-7079

Proprietary Name:

Legion Narrow Oxinium *CR* and *PS* Femoral Components and Instruments

Common Name:

Total Knee Prosthesis

Classification Name and Reference:

21 CFR 888.3560, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Device Class

Class II

Device Product Code and Panel Code:

JWH / Orthopedics / 87

Device Description:

The implant devices described in this premarket notification are comprised of **Legion Narrow Oxinium Cruciate Retaining (CR) and Posterior Stabilized (PS) Femoral Components**. All described implant components are manufactured from oxidized zirconium alloy material (trade name: Oxinium). The subject devices are available in the following configurations and sizes:

Device Type	Hand	Available Sizes
Legion Narrow Oxinium **CR** Femoral Components	Left	3, 4, 5 and 6
Legion Narrow Oxinium **CR** Femoral Components	Right	3, 4, 5 and 6
Legion Narrow Oxinium **PS** Femoral Components	Left	3, 4, 5 and 6
Legion Narrow Oxinium **PS** Femoral Components	Right	3, 4, 5 and 6

Device specific instruments are also described in this premarket notification in select sections and exhibits.

Intended Use:

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; 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 incompetent and the collateral ligaments remain intact.

Smith & Nephew, Inc. **Legion Narrow Oxinium CR and PS Femoral Components** are indicated for single use only and for use only with bone cement.

Technological Characteristics:

Components comprising **Legion Narrow Oxinium CR and PS Femoral Components** are very similar to the legally marketed devices listed below. When compared to the predicates, the proposed devices share very similar or identical Indications for Use, intended use, are manufactured from similar or identical materials, and incorporate very similar technological design characteristics.

Substantial Equivalence Information:

When compared to the *implant* and *device specific instrument* predicate devices listed below, substantial equivalence is based on similarities with regard to overall indications for use, material composition, and technological design characteristics.

- Genesis II Total Knee System – K951987
- Genesis II and Profix Zirconium Femoral Components – K962557
- Legion Primary Knee System – K093746

Preclinical Testing:

To further support a determination of substantial equivalence, various types of pre-clinical testing were conducted on the subject, implantable devices in comparison against one or more of the previously cleared predicate devices described above. The specific types of pre-clinical testing included:

- *Tibiofemoral Constraint Testing* of femorals against interfacing polyethylene articular insert components seated in appropriate metal tibial bases in *A/P Draw, M/L Shear* and *rotary laxity (R/L)*
- *Tibiofemoral Contact Area Testing* of femorals against interfacing polyethylene articular insert components seated in appropriate metal tibial bases
- *Patellofemoral Subluxation Testing* of the femoral to determine the amount of resistance to lateral subluxation of the patellofemoral interface

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

DEC 2 0 2011

Smith & Nephew, Inc.
Orthopaedics Division
% Mr. David Henley
Regulatory Affairs Project Manager
7135 Goodlet Farms Parkway
Cordova, Tennessee 38016

Re: K112941
Trade/Device Name: Legion Narrow Oxinium Cruciate Retaining (CR) and Posterior Stabilized (PS) Femoral Components and Device Specific Instruments
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: October 3, 2011
Received: October 4, 2011

Dear Mr. Henley:

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

Premarket Notification

Indications for Use Statement

510(k) Number (if known): K112941

Device Name: **Legion Narrow Oxinium C/R and P/S Femoral Components**

Indications for Use:

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; 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 incompetent and the collateral ligaments remain intact.

Smith & Nephew, Inc. Legion Narrow Oxinium C/R and P/S Femoral Components are indicated for use only with cement and are single use only devices.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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 Melkerson
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112941