K093746 1/2

Summary of Safety and Effectiveness
VERILAST® Wear Claims for the LEGION® Primary Knee System
Smith & Nephew, Inc.

Contact Person and Address
Jason Sells
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Smith & Nephew, Inc.
Orthopaedic Division
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Date of Summary: April 14, 2010

4/14/2010

Name of Device: LEGION® Primary Knee System
Common Name: Total Knee Prosthesis
Device Classification Name and Reference: 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Device Class: Class II
Panel Code: Orthopaedics/87 JWH
Predicate Devices: Genesis II & Profix Zirconium Femoral Knee Components (K962557); and Crosslinked Polyethylene Articular Inserts (K071071)

Device Description
Subject of this Traditional 510(k) Premarket Notification is a request for long-term *in vitro* wear claims for the Smith & Nephew, Inc. Legion Primary Knee System. The wear claims will be made for the use of a Legion Primary Oxinium femoral component coupled with a 7.5 Mrad cross-linked polyethylene (XLPE) articular insert. The Legion Primary Knee System consists of existing total knee implant devices, and it is important to note that there are no new total knee components being introduced as a result of this Traditional 510(k) premarket notification.

Intended Use
Total knee components are 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. Smith & Nephew, Inc. Legion Primary Knee components are indicated for use only with cement and are single use devices.

Performance Data
In vitro knee simulator wear testing provided in the submission demonstrated that the OXINIUM®/XLPE bearing couple exhibited low wear characteristics in long-term laboratory testing as compared to a control total knee system. The results of in-vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance.

Clinical data was not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence Information

The Legion Primary Knee System consists of existing total knee implants currently marketed by Smith & Nephew. The femoral implant components are substantially equivalent to the Genesis II Oxinium femoral components cleared via K962557. The following, minor modifications were made to the Genesis II Oxinium femoral components in order to develop the subject devices:

- Increased the thickness of the medial posterior condyle to match that of the lateral posterior condyle
- Addition of threaded screw holes for wedge attachment (posterior stabilized design only)
- Addition of anterior wall to femoral box geometry (posterior stabilized design only)
- Increased in height of femoral box geometry (posterior stabilized design only)

The subject femoral components are used with existing Legion articular inserts[1] cleared via K071071.

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for long-term wear claims for the Smith & Nephew, Inc. Legion Primary Knee System. As no new total knee components are being introduced as a result of this premarket notification, the devices are substantially equivalent to knee components currently marketed under K962557 and K071071.

[1] The Genesis II cross-linked polyethylene (XLPE) articular inserts cleared via K071071 are marketed by Smith & Nephew under the Legion brand name.

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

APR 14 2010

Smith & Nephew, Inc.
% Mr. Jason Sells
1450 E Brooks Road
Memphis, Tennessee 38116

Re: K093746
Trade/Device Name: LEGION Primary Knee System
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: April 8, 2010
Received: April 9, 2010

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. 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,

Barbara Brem

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): K093746

Device Name: LEGION® Primary Knee System

Indications for Use:

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Prescription Use		AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)	X		(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 K093746