K091543

510(k) Summary of Safety and Effectiveness
LEGION® Porous Plus HA Primary Femoral Components

Contact Person and Address
Jason Sells
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Orthopaedic Division
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Memphis, Tennessee 38116
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Date of Summary: May 22, 2009

DEC 21 2009

Name of Device: Smith & Nephew Legion Porous Plus HA Primary Femoral Components
Common Name: Femoral Knee Prosthesis
Device Classification Name and Reference: 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (Class II)
Device Product Code: MBH

Device Description
Legion Porous Plus HA Primary Femoral Components are geometrically identical to the Legion Porous Primary femoral components cleared via K073325. This premarket notification seeks only to add a hydroxylapatite (HA) coating to the porous coated areas of the femoral implants. The subject devices will be initially offered in both cruciate retaining (CR) and posterior stabilizing (PS) designs in sizes 1-8 in right and left hand configurations. The subject devices will utilize the same articular inserts as the non-HA coated Legion Porous Primary femoral components cleared via K073325 and will use existing Genesis II tibial baseplate and patellar components cleared via K030612.

Mechanical Testing
A review of the mechanical testing results indicated that the Legion Porous Plus HA Primary Femoral Components are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

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 primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. The Smith & Nephew Legion Porous Plus HA Primary Femoral Components are indicated for use without bone cement and are single use devices.

Substantial Equivalence Information
The Smith & Nephew Legion Porous Plus HA Primary Femoral Components are similar in overall design, indications, and materials to the Legion Porous Primary femoral components cleared via K073325. The subject devices feature the same HA coating as devices in the Genesis II Porous Plus HA Knee System cleared via K032683.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

DEC 21 2009

Re: K091543
Trade/Device Name: Legion Porous Plus HA Primary Femoral Components
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: December 8, 2009
Received: December 9, 2009

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.

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: LEGION Porous Plus HA Primary Femoral Components

Indications for 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 primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. The Smith & Nephew Legion Porous Plus HA Primary Femoral Components are indicated for use without bone 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)

FOR M. MELKERSON

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

510(k) Number K091543