K093991

p. 1/2

510(k) Summary

We are **smith&nephew**

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
	APR 1 5 2010
Date of Summary:	April 8, 2010
Contact Person and Address:	Shereen Myers, Regulatory Affairs Specialist T (901) 399-6325 F (901) 566-7075
Name of Device:	Smith & Nephew Orthopaedics AG SLR-PLUS Standard and Lateral Femoral Stems
Common Name:	Hip Stem
Device Classification Name and Reference:	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR 878.3300 Surgical mesh 21 CFR 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LZO, subsequent LPH, MBL, MEH, JDI, JDJ

Device Description

Subject of this Traditional 510(k) premarket notification is the SLR-PLUS Standard and Lateral Femoral Stems. The subject devices are intended for primary hip arthroplasties and to replace previously failed femoral hip arthroplasties. The SLR-PLUS Standard Femoral Stems are designed for prosthetic arthroplasty in primary and revision surgery. The SLR-PLUS Lateral stem has been designed to optimize the lateralization of the femur (offset) in hip arthroplasty surgery. Both stems are manufactured from Ti-6Al-7Nb titanium alloy.

Technological Characteristics

A review of the mechanical data indicates that the SLR-PLUS Standard and Lateral Femoral Stems are capable of withstanding expected *in vivo* loading without failure.

Intended Use

The SLR-PLUS Hip Stem is indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck

fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew Orthopaedics AG SLR-PLUS Hip Stems are intended for single use only.

Substantial Equivalence Information

The substantial equivalence of the SLR-PLUS Femoral Stems is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate systems:

- Smith & Nephew Orthopaedics AG SL-PLUS Standard and Lateral Hip Stems (K072852)
- Smith & Nephew Anthology Hip Stem (K052792)
- SL-PLUS AND SLR-PLUS Stems (K001942)

The following tests were used as a basis for the determination of substantial equivalence:

- Neck fatigue testing per ASTM F 2068-03 and ISO 7206-6
- Distal fatigue testing per ISO 7206-4/8
- Range of Motion per EN ISO 21535

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

Smith & Nephew, Inc.
Orthopaedic Division
% Ms. Shereen Myers
Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

APR 1 5 2010

Re: K093991
Trade/Device Name: SLR-PLUS Standard and Lateral Femoral Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, LPH, MBL, MEH, JDI, JDJ
Dated: April 8, 2010
Received: April 9, 2010

Dear Ms. Myers:

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,

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

Enclosure

K093991

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K093991

Device Name: SLR-PLUS Standard and Lateral Femoral Stems

Indications for Use:

The SLR-PLUS Hip Stem is indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew Orthopaedics AG SLR-PLUS Hip Stems are intended for single use only.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(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 K093991