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510(K) Summary
Smith & Nephew SL PLUS Standard and Lateral Femoral Hip Stem

JUN - 9 2008

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6017
CONTACT PERSON:	Nicholas B. Tabrizi
DATE SUMMARY PREPARED:	September 6, 2007
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew SL PLUS Standard and Lateral Femoral Hip Stem
COMMON OR USUAL NAME:	Total Hip Joint, Femoral Component, Cementless
CLASSIFICATION NAME:	21 CFR 888.3353, LZO — Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
	21 CFR 888.3390, KWY — Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
	21 CFR 888.3360, LWJ — Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
DEVICE CLASS:	Class II
PANEL CODE:	Orthopaedics/87/LWJ, LZO, KWY

A. INTENDED USE:

The SL-PLUS Stem is intended for advanced hip joint wear due to degenerative, post-traumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head.

The SL-PLUS Lateralized Stem is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute).

These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

B. DEVICE DESCRIPTION:

Subject of this premarket notification is the SL-PLUS Standard and Lateral Hip Stems. The overall design is based on the SL-PLUS Standard and SL-PLUS Lateralized Stem cleared in K001942 and K021178 respectively.

Currently, the SL-PLUS Standard Femoral Stems are of a double taper design and are manufactured from Ti-6Al-7Nb titanium alloy according to ASTM F1295-05 and ISO 5832-11. The primary stem SL-PLUS is available in 14 size options.

The SL-PLUS lateralized version is an additional 12 sizes, sizes 1 through 12, of lateralized stems to the SL-PLUS Stems, which were cleared for marketing by FDA on 7/25/00 (K001942). These stems allow for a larger offset from 6 mm (size 1) up to 8.5 mm (size 12) compared to the standard SL-PLUS Stem, thus giving the surgeon a further option to meet the patient's anatomy. The Caput Collum Diaphysis (CCD) angle is 123° compared to 131° for the standard SL-PLUS Stem. The material and surface characteristics remain unchanged for the lateralized stem as compared to the standard stem.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The overall designs and the indications for use for the Smith & Nephew SL PLUS Standard and Lateral Femoral Stem are substantially equivalent to the PLUS Orthopedics SL-Plus and SL-Plus Lateralized Stems cleared for market under 510(k) Notifications K001942 and K021178, respectively.

The Smith & Nephew SL PLUS Standard and Lateral Femoral Hip Stems are similar to the following commercially available devices regarding design features, overall indications, and materials:

Manufacturer	Description	510(K)	Clearance Date
Encore Orthopedics, Inc.	SL-PLUS AND SLR-PLUS	K932481	06/08/94
PLUS Orthopedics.	SL-PLUS AND SLR-PLUS	K001942	07/25/00
PLUS Orthopedics	SL-PLUS Lateralized	K021178	05/14/02

D. SUMMARY OF TECHNOLOGICAL COMPARISON:

The intended use, design, and materials of the Smith & Nephew SL PLUS Standard and Lateral Femoral Hip Stems are substantially equivalent to the previously cleared PLUS Orthopedics SL-Plus and SLR-Plus, and the SL-PLUS Lateralized Stems (K001942 & K021178). Design Control Activities have been completed and the results indicated that the subject device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2008

Smith & Nephew, Inc.
Orthopaedic Division
c/o Mr. Nicholas B. Tabrizi
Regulatory Affairs Specialist II
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K072852
Trade/Device Name: Smith & Nephew SL-PLUS Standard and Lateral Femoral Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented
Regulatory Class: Class II
Product Code: LZO, KWY, LWJ
Dated: May 30, 2008
Received: June 3, 2008

Dear Mr. Tabrizi:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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Indications for Use

510(k) Number (if known): K072852

Device Name: SL-PLUS Standard and Lateral Hip Stems

Indications for Use:

The SL-PLUS Stem is intended for advanced hip joint wear due to degenerative, post-traumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head.

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These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

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)

Mark N. Milleresi

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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