

JUL 19 2012

510(k) Summary
SL-PLUS° Standard and Lateral Femoral Stems with Ti/HA

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	January 23, 2012
Contact Person:	John Connor, Regulatory Affairs Specialist T (901) 399-5944 F (901) 566-7961
Name of Device:	SL-PLUS° Standard and Lateral Femoral Stem with Ti/HA
Common Name:	Total Hip Joint, Femoral Component, Cementless
Device Classification Name and Reference:	21 CFR 888.3353 – Hip joint metal/polymer/metal semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3390 – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LZO, KWY, LWJ

Device Description

The SL-PLUS° Standard and Lateral Stems with Ti/HA are based on the uncoated design of SL-PLUS° Standard and Lateral Femoral Stems cleared via K072852. The subject stems are made from forged titanium alloy Ti-6Al-4Nb with a double coating (triple layer): titanium plasma sprayed coating (two layers) with an additional thin layer of hydroxyapatite.

Intended Use

The SL-PLUS° Standard Femoral Stem with Ti/HA 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 with Ti/HA 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.

Technological Characteristics

A review of the mechanical data indicates that the SL-PLUS[®] Standard and Lateral Femoral Stems with Ti/HA are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information

The overall design, materials, and indications for use for the SL-PLUS[®] Standard and Lateral Femoral Stems with Ti/HA are substantially equivalent to the following commercially available predicate devices.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew Orthopaedics AG	SL-PLUS [®] Standard and Lateral Femoral Stems	K072852	2/9/09
Smith & Nephew Orthopaedics AG	POLARCUP [®] Dual Mobility System	K110135	10/14/11

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

- Stem Fatigue Testing
- Neck Fatigue Testing

All tests which are in relation to the surface characterization (physical, chemical or mechanical) are discussed in detail in the Ti/HA Coating Master File **MAF – 1762, Amendment 1** and are not included in this dossier.

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the SL-PLUS[®] Standard and Lateral Femoral Stems with Ti/HA. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the commercially available predicate devices listed above.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Mr. John Connor
Regulatory Affairs Specialist
1450 Brooks Rd.
Memphis, TN 38116

JUL 19 2012

Re: K120211

Trade/Device Name: SL-PLUS Standard and Lateral Femoral Stem with Ti/HA
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/polymer/metal semi-constrained cemented or nonporous
uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, KWY, LWJ
Dated: July 12, 2012
Received: July 13, 2012

Dear Mr. Connor:

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

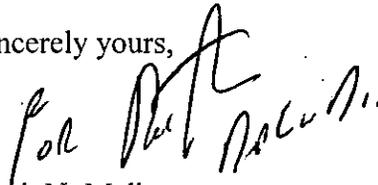
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and 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

**Premarket Notification
Indications for Use Statement**

510(k) Number (if known): K120211 (pg 1/1)

Device Name: SL-PLUS[®] Standard and Lateral Femoral Stem with Ti/HA

Indications for Use:

The SL-PLUS[®] Standard Femoral Stem with Ti/HA is intended for advanced hip joint wear due to degenerative, post-traumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head.

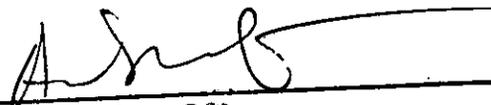
The SL-PLUS[®] Lateralized Stem with Ti/HA is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute).

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.

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 K120211