Smith & Nephew, Inc. FOOTPRINT Ultra PK 4.5mm and 5.5mm Suture Anchor, SL
Special 510(k) Premarket Notification (K123579)

510(k) Summary **Date prepared: January 11, 2013** **JAN 2 3 2013**

Submitter Information	Contact Information
Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810	Catherine Kilshaw Senior Regulatory Affairs Specialist Phone: (508) 337-4104 Fax: (978) 749-1443

Device Name (Unmodified)	
Trade or proprietary name	FOOTPRINT Ultra PK Suture Anchor 4.5 mm, SL FOOTPRINT Ultra PK Suture Anchor 5.5mm, SL
Common or usual name	Soft Tissue Fixation Device (MBI)
Classification name	21 CFR §888.3040 Fastener, fixation, nondegradable, soft tissue

Legally Marketed Predicate Device

The Smith & Nephew FOOTPRINT Ultra PK Suture Anchor, SL is substantially equivalent in intended use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

K113274 **FOOTPRINT Ultra PK Suture Anchor**
(cleared March 6, 2012)

K093897 **SMITH & NEPHEW FOOTPRINT Ultra PK Suture Anchor**
(cleared March 4, 2010)

Device Description

The Smith & Nephew FOOTPRINT Ultra PK Suture Anchor, SL consists of four assembled components; a non-absorbable suture anchor, a suture anchor insertion device, a stay suture, and a suture threader. The FOOTPRINT Ultra PK Suture Anchor is not preloaded with suture, but rather preassembled to an insertion device and held in place with a stay suture. The anchor accommodates up to four (4) strands of ULTRABRAID #2 suture.

Indications for Use

The Smith & Nephew, Inc. FOOTPRINT Ultra PK Suture Anchor, SL is intended for use in the fixation of soft tissue to bone for the following indications:

Shoulder
Rotator Cuff repair, Bankart repair, Slap lesion repair, Biceps Tenodesis, Acromio-Clavicular separation, Deltoid repair, and Capsular shift or capsulolabral reconstruction

Foot and Ankle

Lateral stabilization, Medial stabilization, Achilles tendon repair, Hallux valgus reconstruction, Mid-foot reconstruction, Metatarsal ligament repair

Knee

Medial collateral ligament repair, Lateral collateral ligament repair, Patellar tendon repair, Posterior oblique ligament repair, Iliotibial band tenodesis

Technological Characteristics

The Smith & Nephew FOOTPRINT Ultra PK 4.5mm and 5.5mm Suture Anchor, SL is substantially equivalent in design and fundamental scientific technology to the defined predicate devices and raise no new issues of safety and efficacy.

Performance Data

Mechanical insertion test data demonstrates the device has met the performance specifications and therefore, is considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Smith & Nephew, Incorporated
% Ms. Catherine Kilshaw
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Letter dated: January 23, 2013

Re: K123579
Trade/Device Name: FOOTPRINT Ultra PK Suture Anchor, SL
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 21, 2012
Received: December 26, 2012

Dear Ms. Kilshaw:

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

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

Enclosure

8. Indications for Use Statement

510(k) Number (if known): K123579

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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)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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