K123393

APR 1 1 2013

510(k) Summary
Smith & Nephew, Inc. HEALICOIL Absorbable Suture Anchor

Prepared: April 3, 2013

Submitter Information	Contact Information
Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810	Sue Dahlquist Manager, Regulatory Affairs Phone: (978) 749-1622 Fax: (978) 749-1443

Device Name & Classification	
Proprietary Name	HEALICOIL Absorbable Suture Anchor
Common Name	Soft Tissue Fixation Device
Classification Name	Fastener, fixation, biodegradable, soft tissue
Classification Regulation	21 CFR 888.3030
Class	II
Product Code(s)	MAI
Panel	Orthopedic

Device Description

The HEALICOIL Absorbable Suture Anchor is a bioabsorbable suture anchor provided with up to three strands of non-absorbable sutures, pre-loaded on an insertion device and is available in two sizes, 4.75mm and 5.5mm.

Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	HEALICOIL PK Suture Anchor	K113294	1/20/12
Smith & Nephew, Inc.	Osteoraptor OS Suture Anchor	K101459	1/27/11
Smith & Nephew, Inc.	TwinFix AB Anchor	K032197	8/8/03
DePuy Mitek	Bioknotless Anchor Lupine BR Anchor	K070925	5/2/07
Linvatec Corp.	Bioanchor	K042778	11/4/04

Technological Characteristics

The Smith & Nephew HEALICOIL Absorbable Suture Anchor is substantially equivalent in Intended Use and Fundamental Scientific Technology to the legally marked predicate devices in commercial distribution and raises no new issues of safety and efficacy.

Summary Performance Data

The performance testing conducted demonstrates that the insertion strength and pull-out strength of the HEALICOIL Absorbable Suture Anchor are substantially equivalent to the Smith & Nephew HEALICOIL PK Suture Anchor and the Osteoraptor OS Suture Anchor. And, the *in vitro* degradation of the device is substantially equivalent to the predicate devices.

Intended Use

The Smith & Nephew HEALICOIL Absorbable Suture Anchor is intended for use for the reattachment of soft tissue to bone for the following indications:

<u>Shoulder</u>
- Bankart lesion repairs
- Slap lesion repairs
- Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

<u>Knee</u>

Extra-capsular repairs:
- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament

Patellar realignment and tendon repairs:
- Vastus medialis obliquous advancement

Iliotibial band tenodesis.

<u>Foot & Ankle</u>
- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstruction
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions

<u>Elbow</u>

Ulnar or radial collateral ligament reconstructions

Lateral epicondylitis repair

Biceps tendon reattachment

Substantial Equivalence Information

The substantial equivalence of the HEALICOIL Absorbable Suture Anchor is based on similarities in indications for use, design features, operational principles, material composition, and performance to the predicate devices listed in the table above. Based on the similarities to the predicates, the HEALICOIL Absorbable Suture Anchor is substantially equivalent to its predicates.

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

April 11, 2013

Smith & Nephew, Incorporated
% Ms. Susan Dahlquist
Manager, Regulatory Affairs
150 Minuteman Road
Andover, Massachusetts 01810

Re: K123393
Trade/Device Name: Smith & Nephew HEALICOIL Absorbable Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: March 8, 2013
Received: March 13, 2013

Dear Ms. Dahlquist:

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 contact 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. 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 Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123393

Device Name: Smith & Nephew HEALICOIL Absorbable Suture Anchor

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Prescription Use ___x___ AND/OR Over-The-Counter Use

(Per 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)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices