K093844

SECTION IV
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92(a)(1) upon which the substantial equivalence is based.

Smith & Nephew TWINFIX Ultra HA Suture Anchor

APR - 1 2010

Date Prepared: December14, 2009

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover MA, 01810

B. Company Contact

Christina Flores

Regulatory Affairs Specialist II

Phone: (508) 261-3705

FAX: (508) 261-3620

C. Device Name

Trade Name: TWINFIX Ultra HA Suture Anchor

Common Name: Suture Anchor

Classification Name: Fastener, fixation, bioabsorbable, soft tissue

D. Predicate Devices

The Smith & Nephew TWINFIX Ultra HA Anchor is substantially equivalent in Intended Use and fundamental scientific technology to the following legally marketed Smith & Nephew anchors: Twinfix AB 5.0 (K011299), Twinfix AB 6.5 (K032197), Twinfix FT PK (072785), and Osteoraptor (K082215).

E. Description of Device

The TWINFIX Ultra HA is a suture anchor manufactured from PLLA-HA and is offered in diameters of 4.5, 5.5, and 6.5 mm sizes. The screw-in anchor is preloaded with ultra high molecular weight polyethylene suture preassembled onto a stainless steel inserter.

F. Intended Use

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

Shoulder:

Bankart repairs
SLAP lesion repairs
Capsular shift or capsulolabral reconstructions
Acromioclavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

Foot/Ankle:

Hallux valgus repairs
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions
Metatarsal ligament/tendon repairs/reconstructions
Midfoot reconstructions

Knee:

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

Patellar realignment and tendon repairs:
- Vastus medialis obliquous advancement

Illiotibial band tenodesis.

Elbow:

Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair
Biceps tendon reattachment

G. Comparison of Technological Characteristics

The Smith & Nephew TWINFIX Ultra PK suture anchor is substantially equivalent in intended use, technological characteristics, and are as safe and as effective as their currently marketed predicate devices, the Smith & Nephew Twinfix AB 5.0 (K011299), the Twinfix AB 6.5 (K032197), the Twinfix FT PK (072785), and the Osteoraptor anchors (K082215).

H. Summary Performance Data

The performance testing conducted demonstrates that the insertion and fixation properties of the Smith & Nephew TWINFIX Ultra HA suture anchors are substantially equivalent to the predicates; Twinfix AB 5.0 cleared via K011299and the Twinfix AB 6.5 cleared via K032197. The testing also demonstrates that the differences in the new device and the predicate devices do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
c/o Ms. Christina Flores
Regulatory Affairs Specialist II
130 Forbes Boulevard
Mansfield, Massachusetts 02048

APR 0 1 2010

Re: K093844
Trade/Device Name: TWINFIX Ultra HA 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 17, 2010
Received: March 18, 2010

Dear Ms. Flores:

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.

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 (240) 276-3150 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

Indications for Use

510(k) Number (if known): K093844

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Foot & Ankle:
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- Achilles tendon repairs/reconstruction
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Knee:
- Extra-capsular repairs:
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs:
  - Vastus medialis obliquous advancement
- Iliotibial band tenodesis

Elbow:
- Ulnar or radial collateral ligament reconstructions
- Lateral epicondylitis repair
- Biceps tendon reattachment

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)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093844