K100159

APR 19 2010

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 upon which the substantial equivalence is based.

Smith & Nephew TWINFIX Ultra PK Suture Anchor

Date Prepared: January 19, 2010

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 Ti Suture Anchor

Common Name: Suture Anchor

Classification Name: 888.3040 Smooth or Threaded Metal Bone Fixation Fasteners

D. Predicate Devices

The Smith & Nephew TWINFIX Ultra Ti Anchor is substantially equivalent in Intended Use and fundamental scientific technology to the legally marketed Smith & Nephew TWINFIX Ultra PK Suture Anchor cleared via K093226 and the TWINFIX Ti 5.0 Suture Anchor cleared via K972326.

E. Description of Device

The TWINFIX Ultra Ti is a suture anchor manufactured from Titanium alloy and is offered in diameters of 4.5, 5.5, and 6.5 mm sizes. The anchor is preloaded with suture preassembled onto a stainless steel inserter.

F. Intended Use

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

Shoulder:
- Bankart lesion 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/reconstruction
Midfoot reconstructions
Metatarsal ligament/tendon repairs/reconstructions

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

G. Comparison of Technological Characteristics

The Smith & Nephew TWINFIX Ultra Ti suture anchor is substantially equivalent in intended use and technological characteristics to its currently marketed predicate devices, the Smith & Nephew TWINFIX Ultra PK (K093226) and the TWINFIX Ti 5.0 (K972326). The minor modifications to length, thread profile, and anchor/inserter interface do not introduce any new questions of safety or effectiveness.

H. Summary Performance Data

The critical functional parameters for suture anchors are adequate insertion and fixation (pull-out) strength. Non-clinical testing that included insertion and pull-out strength was performed and the results demonstrate that the insertion and fixation properties of the Smith & Nephew TWINFIX Ultra Ti suture anchor are substantially equivalent to the predicate TWINFIX Ultra PK suture anchor, cleared via K093226. 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

Public Health Service

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

APR 19 2010

Smith & Nephew Inc., Endoscopy Division
% Ms. Christina Flores
Regulatory Affairs Specialist II
150 Minuteman Road
Andover, Massachusetts 01810

Re: K100159
Trade/Device Name: Smith & Nephew TWINFIX Ultra Ti Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded bone fixation fasteners
Regulatory Class: II
Product Code: MBI
Dated: January 19, 2010
Received: January 20, 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. 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,

Barbara Bucher for

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): K100159

Device Name: Smith & Nephew TWINFIX Ultra Ti Suture Anchor

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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)

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

510(k) Number K100159