K032197 PAGE 1/2

AUG - 8 2003

Endoscopy Division

Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
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Smith@Nephew

SECTION V
510(k) Summary

Twin Fix AB™ 6.5 mm suture anchor

Date Prepared: June 15, 2003

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810
508. 261.3699

B. Company Contact

Jason Bilobram
Regulatory Affairs Manager

C. Device Name

Trade Name:	Twin Fix AB 6.5 mm anchor
Common Name:	Absorbable Suture Anchor
Classification Name:	Class II, Fastener, Fixation, Biodegradable, Soft Tissue Product Code MAI

D. Predicate Devices

5.0 mm Absorbable Polymer Anchor (K011299)
Proprietary Name: Twin Fix AB 5.0 mm suture anchor

E. Description of Device

The Twin Fix AB 6.5 mm anchor is a bi-lobed, bioabsorable anchor to which multiple USP No. 2 absorbable or non-absorbable sutures are attached.

F. Intended Use

The Twin Fix AB 6.5 mm anchor is a bioabsorable suture anchor utilized for the reattachment of soft tissue to bone.

The indications for the Twin Fix AB 6.5 mm anchor are:

Shoulder:
1. Bankart Lesion Repair
2. Slap Lesion Reapir
3. Acromioclavicular separation repairs
4. Rotator Cuff Repair
5. Capsular shift or capsulolabral reconstruction
6. Biceps tenodesis
7. Deltoid Repair

Foot and Ankle:
1. Hallux Valgus repair
2. Medial or Lateral instability repairs/reconstruction
3. Achilles tendon repair/reconstruction
4. Midfoot reconstruction
5. Metatarsal ligament/tendon repairs/reconstruction

Elbow, Wrist, and Hand:
1. Scapholunate ligament reconstruction
2. Ulnar or radial collateral ligament reconstruction
3. Lateral epicondylitis repair
4. Biceps tendon reattachment

Knee:
1. Extra-capsular Repairs:
   - 1a. Medial Collateral Repair
   - 1b. Lateral Collateral Ligament
   - 1c. Posterior Oblique Ligament
2. Iliotibial band tenodesis
3. Patellar realignment and tendon repairs, including vastus medialis obliquos advancement

G. Comparison of Technological Characteristics

The Twin Fix AB 6.5 mm anchor is identical in design, operating principle, material and intended use to the Twin Fix AB 5.0 mm anchor.

Jason Bilobram

Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Mr. Jason Bilobram
Regulatory Affairs Manager
Smith & Nephew, Inc.
Endoscopy Division
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K032197
Trade Name: Twin Fix AB™ 6.5mm Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI
Dated: July 17, 2003
Received: July 18, 2003

Dear Mr. Bilobram:

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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K032197

Device Name: 6.5 mm Absorbable Polymer Anchor
(Proprietary Name) Twin Fix™ AB 6.5 mm anchor

Intended Use: Reattachment of soft tissue to bone

Indications for Use:

Shoulder:
1. Bankart Lesion Repair
2. SLAP Lesion Repair
3. Acromioclavicular separation repairs
4. Rotator Cuff Repair
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   - 1c. Posterior Oblique Ligament
2. Iliotibial band tenodesis
3. Patellar realignment and tendon repairs, including vastus medialis obliquos advancement

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter ____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 1-2-96)

510(k) Number K032197