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.

TWINFIX FT PK

Date Prepared: September 28, 2007

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover MA, 01810

DEC 1 0 2007

B. Company Contact

Deana Boushell
Principle Regulatory Affairs Specialist
Phone: (508) 337-4036
FAX: (508) 261-3620

C. Device Name

Trade Name:	TWINFIX FT PK
Common Name:	Suture Anchor
Classification Name:	Fastener, Fixation, Non-degradable, soft tissue

D. Predicate Devices

The TWINFIX FT PK Suture Anchor is substantially equivalent to the Smith & Nephew KINSA RC (K070908) and TWINFIX AB (011219).

E. Description of Device

Preloaded 5.5/6.5 mm suture anchor manufactured from PEEK (polyaryletherkeone) incorporating ultra high molecular weight polyethelene suture on a stainless steel inserter.

F. Intended Use

The suture anchors are intended for the fixation of soft tissue to bone.

G. Comparison of Technological Characteristics

Device Characteristics	Predicate Devices		Proposed Devices
	TWINFIX AB	KINSA RC	TWINFIX FT PK
Device Design/Principles of Operation	Screw in Suture Anchor	Tap and Twist Suture Anchor	Tap and Twist Suture Anchor
Materials	PLLA with Polyethelene Suture	PEEK with Polyethelene Suture	PEEK with Polyethelene Suture
Sterilization Method	EO	EO	EO
Intended Use	Attachment of soft tissue to bone	Attachment of soft tissue to bone	Attachment of soft tissue to bone
Indications for Use	Reattachment of soft tissue to bone in the Shoulder, Foot, Ankle, Elbow, Knee	Reattachment of soft tissue to bone in the rotator cuff.	Reattachment of soft tissue to bone in the Shoulder, Foot, Ankle, Elbow, Knee

H. Summary Performance Data

The performance testing conducted includes bench testing that demonstrates substantial equivalence to KINSA RC and TWINFIX AB.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2007

Smith & Nephew, Inc., Endoscopy Division
% Ms. Deana Boushell
150 Minuteman Road
Andover MA 01810

Re: K072785
Trade/Device Name: TwinFix FT PK
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, JDR
Dated: September 28, 2007
Received: October 1, 2007

Dear Ms. Boushell:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072785

Device Name: TWINFIX FT PK

Indications For Use:

The Smith & Nephew TWINFIX FT PK suture anchors are intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder
- Bankhart Repair
- SLAP lesion repairs
- Capsular Shift or capsulolabral Reconstructions
- Acromioclavicular separation repairs
- Deltoid Repairs
- Rotator Cuff tear repairs
- Biceps tenodesis

Foot and Ankle
- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions

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

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

Prescription Use ___x_____ AND/OR Over-The-Counter Use No

(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 General, Restorative and Neurological Devices

510(k) Number K072785