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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.

2.0 PK Suture Anchor **T** and 2.0 PK Suture Anchor **S**

Date Prepared: May 23, 2008

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

B. Company Contact

Janice Haselton

Sr. Regulatory Affairs Specialist

Phone: 978-749-1494

Fax: 978-749-1443

C. Device Name

Trade Name:	2.0 PK Suture Anchor **T**
	2.0 PK Suture Anchor **S**
Common Name:	Fastener, fixation, non-degradable, soft tissue
Classification Name:	Smooth or threaded metallic bone fixation fastener
Product Code:	MBI
Regulation Number:	21 CFR §888.3040

D. Predicate Devices

The 2.0 PK Suture Anchor **T** and the 2.0 PK Suture Anchor **S** are substantially equivalent to the following legally marketed device in commercial distribution: Smith & Nephew BIORAPTOR 2.3 PK Suture Anchor cleared in K071586 and Arthrex Mini BioSuture Tak™ cleared in K050749/K061863.

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E. Description of Device

The 2.0 PK Suture Anchor **T** and the 2.0 PK Suture Anchor **S** consist of a non-absorbable suture anchor with attached non-absorbable suture(s) preassembled to a stainless steel insertion device, and is provided sterile, for single use only. Both anchor models achieve fixation via ribbed/threaded design characteristics that are consistent with the repair of soft tissue to bone.

F. Intended Use

The 2.0 PK Suture Anchor **T** and 2.0 PK Suture Anchor **S** is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Capsular stabilization- Bankart repair, Anterior shoulder instability, Slap lesion repair, Capsular shift or capsulolabral reconstruction, Acromilavicular separation repairs, Deltoid repairs, Rotator cuff tear repairs and Biceps tenodesis.

Foot/Ankle: Hallux valgus repairs, Medial or lateral instability repairs/reconstruction, Achilles tendon repairs/reconstruction, Mid-foot reconstruction, Metatarsal ligament/tendon repairs/recontructions and Bunionectomy.

Elbow, Wrist, and Hand: Biceps tendon reattachment, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair, and Scapholunate ligament reconstruction,

Knee: Extra-capular repairs -Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament, Patellar realignment and tendon repairs – Vastus medialis obliquous advancement and Illoiotibial band tenodesis.

G. Comparison of Technological Characteristics

The performance testing conducted demonstrates substantial equivalence to the Arthrex Mini BioSuture Tak™suture anchor, cleared in K050749/K061863. The testing also demonstrates that the differences in the new device and the predicate device do not raise any new issues of safety and efficacy

H. Summary Performance Data

The performance testing conducted demonstrates that the insertion and fixation properties of the 2.0 PK Suture Anchor **T** and the 2.0 PK Suture Anchor **S** are substantially equivalent to the Smith & Nephew 2.3 BIORAPTOR and the Arthrex Mini BioSuture Tak™ anchors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2008

Smith & Nephew, Inc.
Endoscopy Division
% Ms. Janice Haselton
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K081511
Trade/Device Name: 2.0 PK Suture Anchor "S" and 2.0 PK Suture Anchor "T"
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC, JDR
Dated: May 28, 2008
Received: May 29, 2008

Dear Ms. Haselton:

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 toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K081511

Device Name: ___2.0 PK Suture Anchor S and 2.0 PK Suture Anchor T__

Indications For Use:

The 2.0 PK Suture Anchor **S** and 2.0 PK Suture Anchor **T** is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Capsular stabilization- Bankart repair, Anterior shoulder instability, Slap lesion repair, Capsular shift or capsulolabral reconstruction, Acromilavicular separation repairs, Deltoid repairs, Rotator cuff tear repairs and Biceps tenodesis.

Foot/Ankle: Hallux valgus repairs, Medial or lateral instability repairs/reconstruction, Achilles tendon repairs/reconstruction, Mid-foot reconstruction, Metatarsal ligament/tendon repairs/recontructions and Bunionectomy.

Elbow, Wrist, and Hand: Biceps tendon reattachment, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair, and Scapholunate ligament reconstruction,

Knee: Extra-capular repairs -Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament, Patellar realignment and tendon repairs – Vastus medialis obliquous advancement and Illoiotibial 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)

Barbara Brenn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081511