SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

MAR 06 2007

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

PLC Suture Anchor

Date Prepared: March 5, 2007

A. Submitter's Name:

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

B. Company Contact

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

C. Device Name

Trade Name:	PLC Suture Anchor
Common Name:	Suture Anchor
Classification Name:	Fastener, Fixation, degradable, soft tissue

D. Predicate Devices

The PLC Suture Anchor is substantially equivalent to the Smith & Nephew BioRaptor Suture Anchor (K053344).

E. Description of Device

Preloaded 2.3 mm suture anchor manufactured from PLC incorporating ultra high molecular weight polyethelene suture on a stainless steel inserter.

F. Indications for Use

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

Shoulder
- Capsular Stabilization
  - Bankhart Repair
  - Anterior Shoulder Instability 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 instablility repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy

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

Hip
- Capsular repair
  - Acetabular labral repair

G. Comparison of Technological Characteristics

The Smith & Nephew PLC Suture Anchor is substantially equivalent to the Smith & Nephew, Inc BIORAPTOR Suture Anchor. The only major difference is the material of the anchor which is PLC, an osteoconductive biodegradable material.

H. Summary Performance Data

The performance testing conducted includes bench and animal testing that demonstrates substantial equivalence to the Smith & Nephew, Inc BIORAPTOR Suture Anchor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
Endoscopy Division
c/o Ms. Deana Boushell
Principal Regulatory Affairs Specialist
150 Minuteman Road
Andover, MA 01810

MAR 06 2007

Re: K063726
Trade/Device Name: PLC 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: HRS, HWC
Dated: December 14, 2006
Received: December 15, 2006

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.

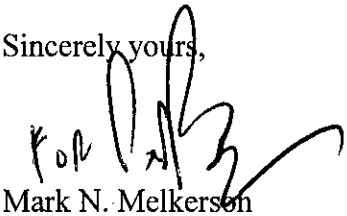
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 240-276-3150 or at its 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

K063726

§I.D

Indications for Use

510(k) Number (if known): K063726

Device Name: PLC Suture Anchors

Indications For Use:

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

Shoulder
- Capsular Stabilization
  - Bankhart Repair
  - Anterior Shoulder Instability Repair
  - SLAP lesion repairs
  - Capsular Shift or capsulolabral reconstructions
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- Achilles tendon repairs/reconstructions
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Hip
- Capsular repair
  - Acetabular labral repair

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 K063726