K053344 page 1 of 2

FEB 2 3 2006

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.

Indication Expansion – TwinFix Ti 2.8 & 3.5/BioRaptor 2.9

Date Prepared: December 1, 2005

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover MA, 01810

B. Company Contact

Deana Boushell

Principle Regulatory Affairs Specialist

Phone: (508) 337-4036

FAX: (508) 261-3620

C. Device Name

Trade Name:	TwinFix Ti 2.8 & 3.5	BioRaptor 2.9
Common Name:	Suture Anchor	Suture Anchor
Classification Name:	Fastener, Fixation, non-degradable, soft tissue	Fastener, Fixation, degradable, soft tissue

D. Predicate Devices

The indication of hip labral repair is substantially equivalent to the currently marketed indications for use of the following legally marketed devices in commercial distribution: The Smith & Nephew TwinFix Ti 2.8 & 3.5 (K972326) BioRaptor 2.9 (K031683).

K033344 P.2 of 4

E. Description of Device

BioRaptor

Preloaded 2.9 mm suture anchor manufactured from PLA (Poly(L-Lactide)) incorporating either ultra high molecular weight polyethelene suture or polyester suture on a stainless steel inserter.

TwinFix

2.8 and 3.5mm titanium suture anchor incorporating either ultra high molecular weight polyethylene or polyester suture. TwinFix anchors are available preloaded on a stainless steel inserter shaft or unassembled. TwinFix anchors are available with or without needles. The TwinFix inserter shaft is available in two lengths, regular and XL.

F. Intended Use

The intended use of the currently available suture anchors remains unchanged. The suture anchors are intended for the fixation of soft tissue to bone.

G. Comparison of Technological Characteristics

There are no changes to the existing devices. Technological Characteristics remain the same.

H. Summary Performance Data

The performance testing conducted includes bench and cadaver testing that demonstrates substantial equivalence for the indication of hip labral to soft tissue repair in other joints.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2006

Ms. Deana Boushell
Principle Regulatory Affairs specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, MA 01810

Re: K053344
Trade/Device Name: TwinFix 2.8mm, 3.5mm and BioRaptor 2.9mm Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, JDR, MAI
Dated: January 27, 2006
Received: January 30, 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.

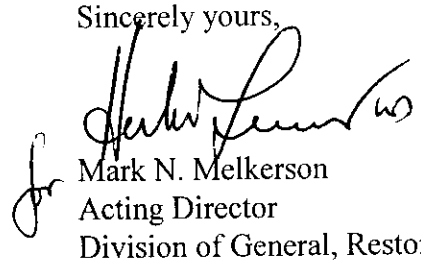
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4639. 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 may be obtained 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,



Mark N. Melkerson
Acting 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): K053344

Device Name: BioRaptor and TwinFix Ti 2.8 & 3.5 Suture Anchors

Indications For Use:

The Smith & Nephew BIORAPTOR 2.9 and TwinFix Ti 2.8 & 3.5 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

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_____