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

OSTEORAPTOR® Suture Anchor

Date Prepared: 04 August 2008

A. Submitter's Name:

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

B. Company Contact

Julie Acker, RAC
Regulatory Affairs Specialist
Phone: (508) 261-3618
FAX: (508) 261-3620

C. Device Name

Trade Name:	OSTEORAPTOR Suture Anchor
Common Name:	Suture Anchor
Classification Name:	Fastener, Fixation, Biodegradable, Soft Tissue
Product Code	MAI
Regulation Number:	21 CFR § 888.3030

D. Predicate Devices

The Smith & Nephew OSTEORAPTOR Suture Anchor is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution: BIORAPTOR 2.9 Anchor (K053344) and BIORAPTOR 2.3 PK Anchor (K071586).

E. Description of Device

The device consists of a suture anchor with attached non-absorbable suture(s) preassembled to an insertion device. This device is provided sterile, for single use only.

F. Intended Use

The Smith & Nephew OSTEORAPTOR Suture Anchor is intended for the reattachment of soft tissue to bone for the following indications:

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

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

Hip
Hip capsule repair
- Acetabular labrum 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

Shoulder
Capsular stabilization
- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions
Acromioclavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

G. Comparison of Technological Characteristics

The Smith & Nephew OSTEORAPTOR Suture Anchor is substantially equivalent to the predicate anchors. The proposed and predicate anchors are similar in design, operate on the same principles, have the same indications and intended use, and exhibit similar fixation properties.

H. Summary Performance Data

The performance testing conducted demonstrates that the insertion and fixation properties of the OSTEORAPTOR Anchor are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2008

Smith & Nephew, Inc.
Endoscopy Division
% Ms. Julie Acker
150 Minuteman Road
Andover, Massachusetts 01810

Re: K082215
Trade/Device Name: Osteoraptor™ 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: JDR, HWC, MAI
Dated: August 4, 2008
Received: August 6, 2008

Dear Ms. Acker:

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 the 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): K082215

Device Name: OSTEORAPTOR® Suture Anchor

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Acromioclavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

Prescription Use X AND/OR Over-The-Counter Use N.

(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 K082215