



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Smith & Nephew, Incorporated  
Ms. Katherine Marcaccio  
Regulatory Affairs Specialist II  
150 Minuteman Road  
Andover, Massachusetts 01810

July 28, 2015

Re: K151105

Trade/Device Name: Smith and Nephew Suture Anchors - 5.0mm Absorbable Polymer Anchor; Smith and Nephew Suture Anchors - TAG Bioraptor Suture Anchor 7209317; 7209318, Smith and Nephew Suture Anchors - Bioraptor 2.3 PK Suture Anchor; Smith and Nephew Suture Anchors - Osteoraptor Suture Anchor; Smith and Nephew Suture Anchors - Twinfix Ultra HA Suture Anchor; Smith and Nephew Suture Anchors - OSTEORAPTOR Curved Suture Anchors; Smith and Nephew Suture Anchors - Ultra Fast-Fix Meniscal Repair System; Ultra Fast-Fix AB Meniscal Repair System; Fast-Fix 360 Meniscal Repair System; Smith and Nephew Suture Anchors - Healicoil Absorbable 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: MAI, HWC, JDR, MBI, GAT

Dated: April 22, 2015

Received: April 24, 2015

Dear Ms. Marcaccio:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number (if known): \_\_\_\_\_

Device Name: Smith & Nephew Suture Anchors – 5.0mm Absorbable Polymer Anchor

Indications for Use:

The Smith & Nephew 5.0 Absorbable Polymer Anchor is intended for use only for the reattachment of soft tissue to bone for the following indications:

<p><b><u>Shoulder:</u></b></p> <ol style="list-style-type: none"> <li>1. Bankart lesion repairs</li> <li>2. SLAP lesion repairs</li> <li>3. Acromioclavicular separation repairs</li> <li>4. Rotator cuff tear repairs</li> <li>5. Capsular shift or capsulolabral reconstructions</li> <li>6. Biceps tenodesis</li> <li>7. Deltoid repairs</li> </ol> <p><b><u>Foot and Ankle:</u></b></p> <ol style="list-style-type: none"> <li>1. Hallux valgus repairs</li> <li>2. Medial or lateral instability repairs/reconstructions</li> <li>3. Achilles tendon repairs/reconstructions</li> <li>4. Midfoot reconstructions</li> <li>5. Metatarsal ligament/tendon repairs/reconstructions</li> </ol>	<p><b><u>Elbow, Wrist, and Hand:</u></b></p> <ol style="list-style-type: none"> <li>1. Scapholunate ligament reconstructions</li> <li>2. Ulnar or radial collateral ligament reconstructions</li> <li>3. Lateral epicondylitis repair</li> <li>4. Biceps tendon reattachment</li> </ol> <p><b><u>Knee:</u></b></p> <ol style="list-style-type: none"> <li>1. Extra-capsular repairs:             <ol style="list-style-type: none"> <li>a. Medial collateral ligament</li> <li>b. Lateral collateral ligament</li> <li>c. Posterior oblique ligament</li> </ol> </li> <li>2. Iliotibial band tenodesis</li> <li>3. Patellar realignment and tendon repairs, including vastus medialis obliquous advancement</li> </ol>
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Prescription Use   X   AND/OR  
(Part 21 CFR 801 subpart D)

Over-the-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



510(k) Number (if known): \_\_\_\_\_

Device Name: Smith & Nephew Suture Anchors – Bioraptor 2.3 PK Suture Anchor

Indications for Use:

These suture anchors are intended for the fixation of soft tissue to bone in the Hip, Shoulder, Foot, Ankle, Elbow, Wrist, Hand and Knee as follows:

**Hip:**

- Hip capsule repair
  - Acetabular labrum reattachment

**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

**Elbow, Wrist, and Hand:**

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

**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

**Foot and Ankle:**

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

Prescription Use   X        AND/OR

Over-the-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 subpart C)

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510(k) Number (if known): \_\_\_\_\_

Device Name: Smith & Nephew Suture Anchors – Osteoraptor Suture Anchor

Indications for 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  
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

Prescription Use   X    
(Part 21 CFR 801 subpart D)

AND/OR

Over-the-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 subpart C)

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510(k) Number (if known): \_\_\_\_\_

Device Name: Smith & Nephew Suture Anchors – Healicoil Absorbable Suture Anchor

Indications for Use:

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

**Shoulder:**

Bankart lesion repairs  
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/reconstruction  
Midfoot reconstructions  
Metatarsal ligament/tendon repairs/reconstructions

**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

**Elbow:**

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

Prescription Use   X   AND/OR Over-the-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## 510(k) Summary

Date Prepared: May 15, 2015

Submitter Information	Contact Information
Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810	Katherine Marcaccio Regulatory Affairs Specialist II Phone: (508) 261-3602 Fax: (978) 749-1443

Device Name (Unmodified)	
Trade or proprietary name	Smith & Nephew Absorbable Suture Anchors
Common or usual name	HWC – Screw, Fixation, Bone JDR – Staple, Fixation, Bone MAI – Fastener, Fixation, Biodegradable, Soft Tissue MBI – Fastener, Fixation, Nondegradable, Soft Tissue GAT - Suture, Nonabsorbable, Synthetic, Polyethylene
Classification name	21 CFR §888.3030 – Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3040 – Smooth or threaded metallic bone fixation fastener 21 CFR §878.5000 - Nonabsorbable poly(ethylene terephthalate) surgical suture

## Legally Marketed Predicate Device

The Smith & Nephew Absorbable Suture Anchors are substantially equivalent in intended use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

510(k) Number	Device Name	Clearance Date
K011299	SMITH AND NEPHEW 5.00MM ABSORBABLE POLYMER ANCHOR	06/27/2001
K031685	TAG ROD BIORAPTOR SUTURE ANCHOR 7209317, 7209318	07/01/2003
K071586	Bioraptor 2.3 PK Suture Anchor	08/17/2007
K082215	Osteoraptor Suture Anchor	11/03/2008
K093844	SMITH & NEPHEW TWINFIX ULTRA HA SUTURE ANCHOR	04/01/2010
K103309	OSTEORAPTOR Curved Suture Anchors	02/03/2011
K121861	SMITH & NEPHEW ULTRA FAST-FIX MENISCAL REPAIR SYSTEM, SMITH & NEPHEW ULTRA FAST-FIX AB MENISCAL	10/18/2012

	REPAIR SYSTEM, SMITH & NEPHEW FAST-FIX 360 MENISCAL REPAIR SYSTEM	
K123393	HEALICOIL SUTURE ANCHOR WITH REGENESORB	04/11/2013

## Device Description

Smith & Nephew Absorbable Suture Anchors are provided in various composite absorbable materials. All of the Smith & Nephew Absorbable Suture Anchors are provided sterile, for single use only. All Smith & Nephew Absorbable Suture Anchors are pre-assembled onto an inserter, sized appropriately to accommodate the indicated procedures. Smith & Nephew Absorbable Suture Anchors come in various configurations, including: with attached non-absorbable suture(s), and with attached stainless steel needle(s). In certain configurations, the Absorbable Suture Anchors are packaged with a guide and threaded dilator. All configurations of the Absorbable Suture Anchors are identical to the identified predicate devices.

## Intended Use

### Smith & Nephew Suture Anchors – 5.0mm Absorbable Polymer Anchor

The Smith & Nephew 5.0 Absorbable Polymer Anchor is intended for use only for the reattachment of soft tissue to bone for the following indications:

#### **Shoulder:**

1. Bankart lesion repairs
2. SLAP lesion repairs
3. Acromioclavicular separation repairs
4. Rotator cuff tear repairs
5. Capsular shift or capsulolabral reconstructions
6. Biceps tenodesis
7. Deltoid repairs

#### **Foot and Ankle:**

1. Hallux valgus repairs
2. Medial or lateral instability repairs/reconstructions
3. Achilles tendon repairs/reconstructions
4. Midfoot reconstructions
5. Metatarsal ligament/tendon repairs/reconstructions

#### **Elbow, Wrist, and Hand:**

1. Scapholunate ligament reconstructions
2. Ulnar or radial collateral ligament reconstructions
3. Lateral epicondylitis repair
4. Biceps tendon reattachment

#### **Knee:**

1. Extra-capsular repairs:
  - a. Medial collateral ligament
  - b. Lateral collateral ligament
  - c. Posterior oblique ligament
2. Iliotibial band tenodesis
3. Patellar realignment and tendon repairs, including vastus medialis obliquous advancement

Smith & Nephew Suture Anchors – TAG Bioraptor Suture Anchor 7209317, 7209318

1. Bankart Lesion Repair
2. Rotator Cuff Repair
3. Capsular Stabilization
4. Anterior Shoulder Instability Repair
5. Repair of ligaments and tendons of the elbow, foot, and ankle including the treatment of:
  - Bunionectomy
  - Lateral ankle instability
  - Biceps tendon reattachment

Smith & Nephew Suture Anchors – Bioraptor 2.3 PK Suture Anchor

These suture anchors are intended for the fixation of soft tissue to bone in the Hip, Shoulder, Foot, Ankle, Elbow, Wrist, Hand and Knee as follows:

**Hip:**

Hip capsule repair

- Acetabular labrum reattachment

**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

**Foot and Ankle:**

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

**Elbow, Wrist, and Hand:**

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

**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

Smith & Nephew Suture Anchors – Osteoraptor Suture Anchor

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  
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

Smith & Nephew Suture Anchors – Twinfix Ultra HA Suture Anchor

The Smith & Nephew TWINFIX Ultra HA Suture Anchor is intended for use for the reattachment of soft tissue to bone for the following indications:

**Shoulder:**

Bankart repairs  
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

**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

**Elbow:**

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

Smith & Nephew Suture Anchors – OSTEORAPTOR Curved Suture Anchors

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

**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

Smith & Nephew Suture Anchors – Ultra Fast-Fix Meniscal Repair System, Ultra Fast-Fix AB Meniscal Repair System, Fast-Fix 360 Meniscal Repair System

The ULTRA FAST-FIX Meniscal Repair System is intended for use as suture retention devices to facilitate percutaneous or endoscopic soft tissue procedures. The ULTRA FAST-FIX System is indicated for use in meniscal repairs and allograft transplant procedures. The ULTRA FAST-FIX System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

The ULTRA FAST-FIX AB Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures. The ULTRA FAST-FIX AB System is indicated for use in meniscal repairs and allograft transplant procedures. The ULTRA FAST-FIX AB System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

The FAST-FIX 360 Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures. The FAST-FIX 360 System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

Smith & Nephew Suture Anchors – Healicoil Absorbable Suture Anchor

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

**Shoulder:**

Bankart lesion repairs  
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/reconstruction  
Midfoot reconstructions  
Metatarsal ligament/tendon repairs/reconstructions

**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

**Elbow:**

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

## Technological Characteristics

Smith & Nephew Absorbable Suture Anchors are substantially equivalent in intended use and fundamental scientific technology to the legally marketed predicate devices in this submission and raises no new issues of safety and efficacy.

## Summary of Performance Data

Ship Testing and Post-Shipment mechanical functional testing for insertion and pullout (fixation) force demonstrates that the Absorbable Suture Anchors are substantially equivalent to the currently marketed predicate devices.

## Substantial Equivalence Information

The substantial equivalence of the Absorbable Suture Anchors is based on identical indications for use, design features, operational principles, material composition, and performance to the predicate devices listed above. Based on the identical features to the predicates, the Absorbable Suture Anchors are substantially equivalent to the predicates.