



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

Smith & Nephew, Incorporated
Katherine Marcaccio
Regulatory Affairs Specialist II
130 Forbes Boulevard
Mansfield, Massachusetts 02048

December 2, 2015

Re: K152566

Trade/Device Name: PEBA Anchor/Suture Combination, 2.0mm Mini-Tac Anchor, Model 10-1629-01, Modification to Twinfix Ti Quick-T, Twinfix FT PK, Twinfix Ultra Ti, Twinfix Ultra PK, Twinfix Ultra HA Suture Anchors, FOOTPRINT Ultra PK Suture Anchors, BIORAPTOR 2.9 Suture Anchor, BIORAPTOR 2.3 PK Suture Anchor, OSTEORAPTOR Suture Anchor, BIORAPTOR Knotless Suture Anchor, HEALICOIL PK Suture Anchor (formerly Next Generation Fully Threaded Suture Anchor), Bioraptor Curved 2.3 PK Suture Anchors

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II

Product Code: MBI

Dated: September 9, 2015

Received: September 10, 2015

Dear Katherine 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152566

Device Name

PEBA Anchor/Suture Combination

Indications for Use (Describe)

This device (PeBA Series and Cinch Series Anchor/Suture Combination) is intended for use only for the fixation of non-absorbable synthetic sutures.

The Cinch Series Anchor/Suture Combination is intended only for the fixation of surgical suture material to the pelvis for the purpose of bladder neck suspensions for female urinary incontinence due to urethral hypermobility of intrinsic sphincter deficiency.

The PeBA Series Anchor/Suture Combination is intended for the fixation of surgical suture material for the following indications:

Shoulder:

1. Bankart lesion repairs
2. SLAP lesion repairs
3. Acromio-clavicular 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
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. Tennis elbow 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 obliquus advancement

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

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Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152566

Device Name

2.0mm Mini-Tac Anchor, Model 10-1629-01

Indications for Use (Describe)

The OBL Preloaded Series Anchor is intended for use only for the fixation of non-absorbable synthetic suture material for the following indications:

Shoulder:

1. Bankart lesion repairs
2. SLAP lesion repairs
3. Acromio-clavicular 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

*Pelvis:

2. Bladder neck suspension procedures

* This indication is marketed separately from the orthopedic indications under the trade name Cinch®

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)

K152566

Device Name

Modification to Twinfix Ti Quick T

Indications for Use (Describe)

The Smith & Nephew TwinFix Ti Quick T is indicated for use as a suture anchor to facilitate percutaneous or endoscopic soft tissue procedures. The Smith & Nephew Suture Anchor is indicated for shoulder, foot, ankle, elbow, knee, wrist, and hand. Examples of such procedures include:

Shoulder:

Bankart lesion repairs, SLAP lesion repairs, acromio-clavicular separation repairs, rotator cuff repairs, capsular shift or capsulolabral reconstructions, biceps tendonesis, and deltoid repairs.

Foot and Ankle:

Hallux Valgus repairs, medial or lateral instability repairs/reconstructions, Achilles tendon repairs/reconstructions, midfoot reconstructions, and metatarsal ligament/tendon repairs/reconstructions.

Elbow, Wrist and Hand:

Scapholunate ligament reconstructions, ulnar or radial collateral ligament reconstructions, tennis elbow repair, and biceps tendon reattachment.

Knee:

Extra-capsular repairs: medial collateral ligament, lateral collateral ligament, and posterior oblique ligament. Iliotibial band tendonesis, and patellar realignment and tendon repairs, including vastus medialis obliquous advancement.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152566

Device Name

Twinfix FT PK

Indications for Use (Describe)

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

Shoulder:

Bankhart Repair

SLAP lesion repairs

Capsular shift or capsulolabral Reconstructions

Acomioclavicular 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

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152566

Device Name

Twinfix Ultra Ti, Twinfix Ultra PK, Twinfix Ultra HA Suture Anchors

Indications for Use (Describe)

The Smith & Nephew TWINFIX Ultra Ti, PK, HA suture anchor families are intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder:

Bankart lesion repairs
SLAP lesion repairs
Acromioclavicular separation repairs
Rotator cuff tear repairs
Capsular shift or capsulolabral reconstructions
Biceps tenodesis
Deltoid repairs

Foot and Ankle:

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

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
Iliotibial band tenodesis
Patellar realignment and tendon repairs:
- Vastus medialis obliquous advancement

Hip:

Abductor tendon repair

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152566

Device Name

FOOTPRINT Ultra PK Suture Anchors

Indications for Use (Describe)

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

Hip:

Hip capsular repair

-Acetabular labral repair

Shoulder:

Capsular Stabilization

- Bankart 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 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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152566

Device Name

BIORAPTOR 2.9 Suture Anchor, BIORAPTOR 2.3 PK Suture Anchor, OSTEORAPTOR Suture Anchor, BIORAPTOR Knotless Suture Anchor

Indications for Use (Describe)

The Smith & Nephew Suture Anchors are intended for the reattachment of soft tissue to bone for the following indications:

Hip

Hip capsule repair

- Acetabular labrum reattachment/reconstruction

Shoulder

Capsular stabilization

- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions

Acromioclavicular separation repairs

Deltoid repairs

Rotator Cuff 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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152566

Device Name

HEALICOIL PK Suture Anchor (formerly Next Generation Fully Threaded Suture Anchor)

Indications for Use (Describe)

The Smith & Nephew Next Generation Fully Threaded PEEK Suture Anchor is intended for use 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

Hip:

Gluteal tendon repairs
- Gluteus medius and gluteus minimus repair

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152566

Device Name

Bioraptor Curved 2.3 PK Suture Anchors

Indications for Use (Describe)

The Smith & Nephew BIORAPTOR Curved 2.3 PK 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

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary 2015

Date Prepared: November 9,

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 Non-Absorbable Suture Anchors
Common or usual name	MBI – Fastener, Fixation, Nondegradable, Soft Tissue
Classification name	21 CFR §888.3040 – Smooth or threaded metallic bone fixation fastener

Legally Marketed Predicate Device

The Smith & Nephew Non-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
K972326	PEBA ANCHOR/SUTURE COMBINATION	02/06/1998
K000797	2.0mm MINI-TAC ANCHOR, MODEL 10-1629-01	04/03/2000
K023021	MODIFICATION TO SMITH & NEPHEW TWINFIX TI QUICK-T	10/04/2002
K072785	Twinfix FT PK	12/10/2007
K102660	BIORAPTOR CURVED 2.3 PK Suture Anchors	12/13/2010
K112526	TWINFIX ULTRA TI, TWINFIX ULTRA PK, TWINFIX ULTRA HA Suture Anchors	01/31/2012
K113274	FOOTPRINT Ultra PK suture anchors	03/06/2012
K113294	SMITH & NEPHEW Healicoil PK Suture Anchor	01/20/2012
K121018	Smith & Nephew, Inc. BIORAPTOR 2.9 Suture Anchor, BIORAPTOR 2.3 PK Suture Anchor, OSTEORAPTOR Suture Anchor, BIORAPTOR Knotless Suture Anchor	06/22/2012

Device Description



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

Intended Use

Smith & Nephew Suture Anchors – PEBA Anchor/Suture Combination

This device (PeBA Series and Cinch Series Anchor/Suture Combination) is intended for use only for the fixation of non-absorbable synthetic sutures.

The Cinch Series Anchor/Suture Combination is intended only for the fixation of surgical suture material to the pelvis for the purpose of bladder neck suspensions for female urinary incontinence due to urethral hypermobility of intrinsic sphincter deficiency.

The PeBA Series Anchor/Suture Combination is intended for the fixation of surgical suture material for the following indications:

Shoulder:

1. Bankart lesion repairs
2. SLAP lesion repairs
3. Acromio-clavicular 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
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. Tennis elbow 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 – 2.0mm MINI-TAC ANCHOR, MODEL 10-1629-01

The OBL Preloaded Series Anchor is intended for use only for the fixation of non-absorbable synthetic suture material for the following indications:

Shoulder:



1. Bankart lesion repairs
2. SLAP lesion repairs
3. Acromio-clavicular 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 obliquus advancement

***Pelvis:**

2. Bladder neck suspension procedures
- * This indication is marketed separately from the orthopedic indications under the trade name Cinch®

Smith & Nephew Suture Anchors – Modification to Twinfix Ti Quick T

The Smith & Nephew TwinFix Ti Quick T is indicated for use as a suture anchor to facilitate percutaneous or endoscopic soft tissue procedures. The Smith & Nephew Suture Anchor is indicated for shoulder, foot, ankle, elbow, knee, wrist, and hand. Examples of such procedures include:

Shoulder:

Bankart lesion repairs, SLAP lesion repairs, acromio-clavicular separation repairs, rotator cuff repairs, capsular shift or capsulolabral reconstructions, biceps tendonesis, and deltoid repairs.

Foot and Ankle:



Hallux Valgus repairs, medial or lateral instability repairs/reconstructions, Achilles tendon repairs/reconstructions, midfoot reconstructions, and metatarsal ligament/tendon repairs/reconstructions.

Elbow, Wrist and Hand:

Scapholunate ligament reconstructions, ulnar or radial collateral ligament reconstructions, tennis elbow repair, and biceps tendon reattachment.

Knee:

Extra-capsular repairs: medial collateral ligament, lateral collateral ligament, and posterior oblique ligament. Iliotibial band tendonsis, and patellar realignment and tendon repairs, including vastus medialis obliquous advancement.

Smith & Nephew Suture Anchors – Twinfix FT PK

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

Shoulder:

Bankhart 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

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



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

repairs:
- Vastus medialis obliquous
advancement
Iliotibial band tenodesis

Smith & Nephew Suture Anchors – Bioraptor Curved 2.3 PK Suture Anchors

The Smith & Nephew BIORAPTOR Curved 2.3 PK 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

Foot and Ankle:

Hallux valgus repairs
Medial or lateral instability

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



repairs/reconstructions
 Achilles tendon repairs/reconstructions
 Midfoot reconstructions
 Metatarsal ligament/tendon
 repairs/reconstructions
 Bunionectomy

Smith & Nephew Suture Anchors – Twinfix Ultra Ti, Twinfix Ultra PK, Twinfix Ultra HA Suture Anchors

The Smith & Nephew TWINFIX Ultra Ti, PK, HA suture anchor families are intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder:

Bankart lesion repairs
 SLAP lesion repairs
 Acromioclavicular separation repairs
 Rotator cuff tear repairs
 Capsular shift or capsulolabral reconstructions
 Biceps tenodesis
 Deltoid repairs

Foot and Ankle:

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

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

Iliotibial band tenodesis
 Patellar realignment and tendon
 repairs:

- Vastus medialis obliquus
 advancement

Hip:

Abductor tendon repair

Smith & Nephew Suture Anchors – FOOTPRINT Ultra PK Suture Anchors

The Smith & Nephew FOOTPRINT Ultra PK suture anchor family is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Rotator cuff repair, Bankart repair, Slap lesion repair, Biceps tenodesis, Acromio-Clavicular separation, Deltoid repair, and Capsular shift or Capsulolabral reconstruction.

Foot/Ankle: Lateral stabilization, Medial stabilization, Achilles tendon repair, Hallux valgus reconstruction, Mid-foot reconstruction, Metatarsal ligament repair.

Knee: Medial collateral ligament repair, Lateral collateral ligament repair, Patellar tendon repair, Posterior oblique ligament repair, Iliotibial band tenodesis.

Hand/Wrist: Scapholunate ligament reconstruction, Ulnar collateral ligament reconstruction, Radial collateral ligament reconstruction.

Elbow: Biceps Tendon reattachment, Ulnar or radial collateral ligament reconstruction.

Hip: Distal row abductor tendon repair.



Smith & Nephew Suture Anchors – HEALICOIL PK Suture Anchor (formerly Next Generation Fully Threaded Suture Anchor)

The HEALICOIL PK Suture Anchor (formerly Smith & Nephew Next Generation Fully Threaded PEEK Suture Anchor) is intended for use 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

Hip:

Gluteal tendon repairs

- Gluteus medius and gluteus minimus repair

Smith & Nephew Suture Anchors - BIORAPTOR 2.9 Suture Anchor, BIORAPTOR 2.3 PK Suture Anchor, OSTEORAPTOR Suture Anchor, BIORAPTOR Knotless Suture Anchor

The Smith & Nephew Suture Anchors are intended for the reattachment of soft tissue to bone for the following indications:

Hip

Hip capsule repair

- Acetabular labrum reattachment/reconstruction

Shoulder

Capsular stabilization

- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions

Acromioclavicular separation repairs

Deltoid repairs

Rotator Cuff 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 Non-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 Non-Absorbable Suture Anchors are substantially equivalent to the currently marketed predicate devices.

Substantial Equivalence Information

The substantial equivalence of the Non-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 Non-Absorbable Suture Anchors are substantially equivalent to the predicates.