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

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
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 obliqueus 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)
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*
The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
Indications for Use

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 oblique 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*
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, capsulorraphy reconstructions, biceps tendoscopy, 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 tendoscopy, and 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the
time to review instructions, search existing data sources, gather and maintain the data needed and complete
and review the collection of information. Send comments regarding this burden estimate or any other aspect
of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTAFF@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of
information unless it displays a currently valid OMB number."
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
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 oblique 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)
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
Indications for Use

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 oblique 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)
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
Indications for Use

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 oblique advancement
  - Iliotibial band tenodesis

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

- [ ] Prescription Use (Part 21 CFR 801 Subpart D)
- [x] Over-The-Counter Use (21 CFR 801 Subpart C)
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRAStaff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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 oblique 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
Indications for Use

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 obliquus 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)
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
Indications for Use

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 obliquus 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)
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510(k) Summary

Date Prepared: November 9, 2015

Submitter Information

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

Contact Information

Katherine Marcaccio
Regulatory Affairs Specialist II
Phone: (508) 261-3602
Fax: (978) 749-1443

Device Name (Unmodified)

<table>
<thead>
<tr>
<th>Trade or proprietary name</th>
<th>Smith &amp; Nephew Non-Absorbable Suture Anchors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common or usual name</td>
<td>MBI – Fastener, Fixation, Nondegradable, Soft Tissue</td>
</tr>
<tr>
<td>Classification name</td>
<td>21 CFR §888.3040 – Smooth or threaded metallic bone fixation fastener</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>510(k) Number</th>
<th>Device Name</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>K972326</td>
<td>PEBA ANCHOR/SUTURE COMBINATION</td>
<td>02/06/1998</td>
</tr>
<tr>
<td>K000797</td>
<td>2.0mm MINI-TAC ANCHOR, MODEL 10-1629-01</td>
<td>04/03/2000</td>
</tr>
<tr>
<td>K023021</td>
<td>MODIFICATION TO SMITH &amp; NEPHEW TWINFIX TI QUICK-T</td>
<td>10/04/2002</td>
</tr>
<tr>
<td>K072785</td>
<td>Twinfix FT PK</td>
<td>12/10/2007</td>
</tr>
<tr>
<td>K102660</td>
<td>BIORAPTOR CURVED 2.3 PK Suture Anchors</td>
<td>12/13/2010</td>
</tr>
<tr>
<td>K112526</td>
<td>TWINFIX ULTRA TI, TWINFIX ULTRA PK, TWINFIX ULTRA HA Suture Anchors</td>
<td>01/31/2012</td>
</tr>
<tr>
<td>K113274</td>
<td>FOOTPRINT Ultra PK suture anchors</td>
<td>03/06/2012</td>
</tr>
<tr>
<td>K113294</td>
<td>SMITH &amp; NEPHEW Healiccoil PK Suture Anchor</td>
<td>01/20/2012</td>
</tr>
<tr>
<td>K121018</td>
<td>Smith &amp; Nephew, Inc. BIORAPTOR 2.9 Suture Anchor, BIORAPTOR 2.3 PK Suture Anchor, OSTEORAPTOR Suture Anchor, BIORAPTOR Knotless Suture Anchor</td>
<td>06/22/2012</td>
</tr>
</tbody>
</table>

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 tenodesis, 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 obliquus 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
- Acomioclavicular separation repairs
- Deltoid Repairs
- Rotator Cuff tear repairs
- Biceps tenodesis

**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

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

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 obliquis 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 TWINFOX 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

**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 oblique 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.


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

Hip: Distal row abductor tendon repair.
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 oblique 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

**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 oblique 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

---

**Technological Characteristics**
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.