June 25, 2025

Smith & Nephew, Inc.
Crystal Treadway
Sr. Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K251627
Trade/Device Name: BIORAPTOR 2.3 PK Suture Anchor w/ ULTRABRAID (#2) Suture (cobraid blue); BIORAPTOR 2.3 PK Suture Anchor w/ ULTRABRAID (#2) Suture (cobraid black) ; BIORAPTOR 2.3 PK Suture Anchor w/ ULTRABRAID (#2) Suture (white) ; BIORAPTOR CURVED 2.3 PK Suture Anchor w/ ONE 38" ULTRABRAID (#2) Suture (cobraid black); BIORAPTOR CURVED 2.3 PK Suture Anchor w/ ONE 38" ULTRABRAID (#2) Suture (cobraid blue)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 27, 2025
Received: May 28, 2025

Dear Crystal Treadway:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-

devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251627

Device Name

BIORAPTOR◊ 2.3 PK Suture Anchor w/ UL TRABRAID◊ (#2) Suture (cobraid blue);
BIORAPTOR◊ 2.3 PK Suture Anchor w/ ULTRABRAID◊ (#2) Suture (cobraid black);
BIORAPTOR◊ 2.3 PK Suture Anchor w/ ULTRABRAID◊ (#2) Suture (white);
BIORAPTOR◊ CURVED 2.3 PK Suture Anchor w/ ONE 38" ULTRABRAID◊ (#2) Suture (cobraid black);
BIORAPTOR◊ CURVED 2.3 PK Suture Anchor w/ ONE 38" ULTRABRAID◊ (#2) Suture (cobraid blue)

Indications for Use *(Describe)*

The Smith & Nephew BIORAPTOR◊ Suture Anchor is indicated 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 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 BIORAPTOR◊ Curved 2.3 PK Suture Anchors are indicated 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Smith+Nephew

510(k) Summary

Prepared: 25 June 2025

Submitter Information	Contact Information
Smith & Nephew, Inc. Endoscopy Division 150 Minuteman Road Andover, MA 01810	Mrs. Crystal Treadway Sr. Regulatory Affairs Specialist Crystal.Treadway@Smith-nephew.com

Device Name & Classification	
Proprietary Name	BIORAPTOR◊ 2.3 PK Suture Anchor w/ ULTRABRAID◊ (#2) Suture (cobraid blue) BIORAPTOR◊ 2.3 PK Suture Anchor w/ ULTRABRAID◊ (#2) Suture (cobraid black) BIORAPTOR◊ 2.3 PK Suture Anchor w/ ULTRABRAID◊ (#2) Suture (white) BIORAPTOR◊ CURVED 2.3 PK Suture Anchor w/ ONE 38" ULTRABRAID◊ (#2) Suture (cobraid black) BIORAPTOR◊ CURVED 2.3 PK Suture Anchor w/ ONE 38" ULTRABRAID◊ (#2) Suture (cobraid blue)
Common Name	Soft Tissue Fixation Device
Classification Name	Fastener, fixation, biodegradable, soft tissue; fastener, fixation, nondegradable, soft tissue
Classification Regulation	21 CFR 888.3040
Class	II
Product Code(s)	MBI
Panel	Orthopedic

Legally Marketed Predicate Device

The Smith & Nephew BIORAPTOR 2.3 PK and BIORAPTOR Curved 2.3 PK Suture Anchor is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed devices in commercial distribution:

Description	Submission Number	Clearance Date
BIORAPTOR 2.3 PK and BIORAPTOR Curved 2.3 PK Suture Anchor	K152566	02 Dec 2015

Device Description

The Smith & Nephew BIORAPTOR 2.3 PK and BIORAPTOR Curved 2.3 PK Suture Anchors are fixation devices intended to provide secure attachment of soft tissue to bone. The devices consist of a suture anchor with attached non-absorbable suture(s) preassembled to an insertion device. The BIORAPTOR Curved 2.3 PK Suture Anchors are preassembled to a flexible insertion device.

Intended Use

The Smith & Nephew BIORAPTOR◊ Suture Anchor is intended for the reattachment of soft tissue to bone.

The Smith & Nephew BIORAPTOR◊ Curved 2.3 PK Suture Anchor is intended for the reattachment of soft tissue to bone.

Indications for Use

The Smith & Nephew BIORAPTOR◊ Suture Anchor is indicated 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 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

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

Technological Characteristics

	BIORAPTOR 2.3 PK Suture Anchors and the BIORAPTOR Curved 2.3 PK Suture Anchors ***(Subject Device)***	BIORAPTOR 2.3 PK Suture Anchors and the BIORAPTOR Curved 2.3 PK Suture Anchors ***(Predicate Device; K152566)***
Intended Use	The Smith & Nephew BIORAPTOR Suture Anchor is intended for the reattachment of soft tissue to bone.	Same
Indications for Use	The Smith & Nephew Suture Anchor is 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	Same

	- 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 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	
Delivery Method	Arthroscopic	Same
How Supplied	Packaged in thermoformed PETG tray with a PETG retainer and sealed Tyvek lid, Sterile (EtO), Single Use	Same function to maintain sterile barrier as with the predicate device. The subject device is supplied with the same sterilization method and single use labeling as predicate device.
Shelf Life	5 years	Same
MR Compatibility	MR Safe	Same
Anchor Material	100% PEEK (polyetheretherketone)	Same
Suture Material	UHMWPE (ultra high molecular weight polyethylene)	Same
Inserter Shaft Materials	17-4 PH Stainless Steel	Same
Inserter Handle Materials	Polycarbonate and ABS	Same
Method of Anchor Insertion	Inserted into a predrilled hole	Same
Accessories	Nonsterile, reusable and sterile drills and drill guides	Same

The proposed BIORAPTOR 2.3 PK and BIORAPTOR Curved 2.3 PK Suture Anchor is identical in design to the legally marketed BIORAPTOR 2.3 PK and BIORAPTOR Curved 2.3 PK Suture Anchor (K152566). The modifications to the legally marketed predicate device BIORAPTOR 2.3 PK and BIORAPTOR Curved 2.3 PK Suture Anchor (K152566) include changing the packaging from a Tyvek pouch to thermoformed PETG Trays and retainers and Tyvek Lid. The subject device has the same intended use, method of sterilization, materials, and indications for use as the predicate device. The difference in packaging between the subject device and predicate device are minor and raise no new questions of safety of effectiveness.

Performance Data

Non-clinical testing was completed on the subject device for the proposed packaging modification, and the device met all required specifications for each test. Testing included Packaging Design Verification, Usability Evaluation, and Packaging Material Stability. A summary of test acceptance criteria and results have been provided. Results for all tests passed.

Conclusion

The substantial equivalence of the BIORAPTOR 2.3 PK and BIORAPTOR Curved 2.3 PK Suture Anchor is based on identical indications for use, identical design, operational principles, material biocompatibility and composition of the devices, and performance to the predicate devices listed above. Modifications in packaging do not raise additional questions of safety or effectiveness compared to the predicate device. Based on the similarities, BIORAPTOR 2.3 PK and BIORAPTOR Curved 2.3 PK Suture Anchor is substantially equivalent to its predicate.