



January 31, 2025

ZheJiang Decans Medical Devices Co., Ltd.  
Chen Liu  
RA  
No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District  
Jiaxing, Zhejiang 314031  
China

Re: K243665

Trade/Device Name: Crius PEEK Suture Anchor System (Thread-Fix Anchor); Crius PEEK Suture Anchor System (Thread-Fix Ultra Anchor); Crius PEEK Suture Anchor System (Helicoil Anchor); Crius PEEK Suture Anchor System (Pile Anchor)

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener

Regulatory Class: Class II

Product Code: MBI

Dated: November 24, 2024

Received: November 27, 2024

Dear Chen Liu:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**CHRISTOPHER FERREIRA -S**

Christopher Ferreira, MS  
Assistant Director, Biomedical Engineer  
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

## Indications for Use

Submission Number (if known)

K243665

Device Name

Crius PEEK Suture Anchor System (Thread-Fix Anchor);  
Crius PEEK Suture Anchor System (Thread-Fix Ultra Anchor);  
Crius PEEK Suture Anchor System (Helicoil Anchor);  
Crius PEEK Suture Anchor System (Pile Anchor)

Indications for Use (Describe)

The Crius PEEK Suture Anchor System is intended for the fixation of soft tissue to bone in the foot, ankle, hand, wrist, elbow, knee, hip and shoulder.

Crius PEEK Suture Anchor System (Thread-Fix Anchor)

Shoulder:

Rotator Cuff Repairs

Bankart Repair

SLAP Lesion Repair

Biceps Tenodesis

Acromio-Clavicular Separation Repair

Deltoid Repair

Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle:

Lateral Stabilization

Medial Stabilization

Achilles Tendon Repair

Hallux Valgus Reconstruction

Midfoot reconstruction

Metatarsal Ligament Repair

Knee:

Anterior Cruciate Ligament Repair

Medial Collateral Ligament Repair

Lateral Collateral Ligament Repair

Patellar Tendon Repair

Posterior Oblique Ligament Repair

Iliotibial Band Tenodesis

Elbow:

Biceps Tendon Reattachment

Ulnar or Radial Collateral Ligament Reconstruction

Hip:

Capsular Repair

Acetabular labral repair.

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Crius PEEK Suture Anchor System (Thread-Fix Ultra Anchor)

Shoulder:

Rotator Cuff Repairs

Bankart Repair

SLAP Lesion Repair

Biceps Tenodesis

Acromio-Clavicular Separation Repair

Deltoid Repair

Capsular Shift or Capsulolabral Reconstruction

Foot/ Ankle:

Hallux valgus repairs

Medial or lateral instability repairs/reconstructions

Achilles tendon repairs/reconstructions

Midfoot reconstructions

Metatarsal ligament/tendon repairs/reconstructions

Knee:

Medial collateral ligament repair

Lateral collateral ligament repair

Posterior oblique ligament repair

Iliotibial band tenodesis

Patellar realignment and tendon repairs

Elbow:

Ulnar or radial collateral ligament reconstructions

Lateral epicondylitis repair

Biceps tendon reattachment

Hip:

Abductor tendon repair

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Crius PEEK Suture Anchor System (Helicoil Anchor)

Shoulder:

Rotator Cuff Repairs

Bankart Repair

SLAP Lesion Repair

Biceps Tenodesis

Acromio-Clavicular Separation Repair

Deltoid Repair

Capsular Shift or Capsulolabral Reconstruction

Foot/ Ankle:

Hallux valgus repairs

Medial or lateral instability repairs/reconstructions

Achilles tendon repairs/reconstruction

Midfoot reconstructions

Metatarsal ligament/tendon repairs/reconstructions

Knee:

Medial collateral ligament repair

Lateral collateral ligament repair

Posterior oblique ligament repair

Iliotibial band tenodesis

Patellar realignment and tendon repairs

Elbow:

Ulnar or radial collateral ligament reconstructions

Lateral epicondylitis repair

Biceps tendon reattachment

Hip:

Gluteal tendon repairs

- Gluteus medius and gluteus minimus repair

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Crius PEEK Suture Anchor System (Pile Anchor)

Shoulder:

Rotator Cuff Repair

Bankart Repair

SLAP Lesion Repair

Biceps Tenodesis

AcromioClavicular Separation Repair

Deltoid Repair

Capsular Shift or Capsulolabral Reconstruction Foot/

Ankle:

Lateral Stabilization

Medial Stabilization

Achilles Tendon Repair

Metatarsal Ligament Repair/Tendon Repair

HALLUX Valgus Reconstruction

Mid-foot Reconstruction

Bunionectomy

Knee:

Medial Collateral Ligament Repair

Lateral Collateral Ligament Repair

Patellar Tendon Repair

Posterior Oblique Ligament Repair

Iliotibial Band Tenodesis

Elbow:

Biceps Tendon Reattachment

Tennis Elbow Repair

Ulnar or Radial Collateral Ligament Reconstruction

Lateral Epicondylitis Repair

Hand/Wrist:

Scapholunate Ligament Reconstruction

Ulnar or Radial Collateral Ligament Reconstruction

Hip:

Acetabular Labral 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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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## 510K Summary

### Crius PEEK Suture Anchor System

#### 1.SUBMITTER

ZheJiang Decans Medical Devices Co., Ltd.  
No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District, Jiaxing City, Zhejiang Province,314031 P.R. China  
Contact Person:Chen Liu,RA  
Telephone:+86 18132030804  
Email:cliu@decansmd.com  
Date of Preparation:January/23/2025

#### 2.SUBJECT DEVICE

Trade Name: Crius PEEK Suture Anchor System (Thread-Fix Anchor)  
Crius PEEK Suture Anchor System (Thread-Fix Ultra Anchor)  
Crius PEEK Suture Anchor System (Helicoil Anchor)  
Crius PEEK Suture Anchor System (Pile Anchor)

Regulation Number:21 CFR 888.3040

Common Name:Suture Anchor

Classification Name:fastener, fixation, nondegradable, soft tissue

Regulatory Class: Class II

Product Code:MBI

#### 3.PREDICATE DEVICE

Primary Predicate Device

K061665-Arthrex Corkscrew FT by ARTHREX, INC

Additional Predicate Devices

K152566-TWINFIX Ultra PK Suture Anchor by SMITH & NEPHEW, INC.

K113294-HEALICOIL PK Suture Anchor by SMITH & NEPHEW, INC.

K101679-Arthrex PushLock Anchors by ARTHREX, INC

K063479-Arthrex 2.5mm PushLock Anchors by ARTHREX, INC

#### 4.DEVICE DESCRIPTION

The Crius PEEK Suture Anchor System is a soft-tissue to bone fixation device, provided preloaded on a disposable inserter. Crius PEEK Suture Anchor System includes four types Thread-Fix Anchor, Thread-Fix Ultra Anchor, Helicoil Anchor and Pile Anchor. The device is available in varying profile diameters. The system consists of a suture anchor, suture (except for Pile Anchor), and inserter (insertion handle and insertion shaft) and is a sterile, single use device. The anchor body is manufactured from Polyetheretherketone (PEEK). The suture is made from ultra high molecular weight polyethylene (UHMWPE) available in white and blue/white colors. The blue dye used in the suture is Chromium-cobalt-aluminum oxide in accordance with 21

CFR 73.1015 regulations. Sutures supplied meet United States Pharmacopeia (USP) requirements for non-absorbable suture. The insertion shaft is made from 304 stainless steel compliant with ISO 7153-1 and 630 stainless steel compliant with ISO 16061. The surgical instruments are provided non-sterile and shall be sterilized by the end user.

## **5. INDICATION FOR USE**

The Crius PEEK Suture Anchor System is intended for the fixation of soft tissue to bone in the foot, ankle, hand, wrist, elbow, knee, hip and shoulder.

### **Thread-Fix Anchor**

#### Shoulder:

Rotator Cuff Repairs  
Bankart Repair  
SLAP Lesion Repair  
Biceps Tenodesis  
Acromio-Clavicular Separation Repair  
Deltoid Repair  
Capsular Shift or Capsulolabral Reconstruction

#### Knee:

Anterior Cruciate Ligament Repair  
Medial Collateral Ligament Repair  
Lateral Collateral Ligament Repair  
Patellar Tendon Repair  
Posterior Oblique Ligament Repair  
Iliotibial Band Tenodesis

#### Hip:

Capsular Repair  
Acetabular labral repair.

#### Foot/Ankle:

Lateral Stabilization  
Medial Stabilization  
Achilles Tendon Repair  
Hallux Valgus Reconstruction  
Midfoot reconstruction  
Metatarsal Ligament Repair

#### Elbow:

Biceps Tendon Reattachment  
Ulnar or Radial Collateral Ligament Reconstruction

### **Thread-Fix Ultra Anchor**

#### Shoulder:

Rotator Cuff Repairs  
Bankart Repair  
SLAP Lesion Repair  
Biceps Tenodesis  
Acromio-Clavicular Separation Repair  
Deltoid Repair  
Capsular Shift or Capsulolabral Reconstruction

#### Knee:

Medial collateral ligament repair  
Lateral collateral ligament repair

#### Foot/ 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

Posterior oblique ligament repair  
 Iliotibial band tenodesis  
 Patellar realignment and tendon repairs  
 Hip:  
 Abductor tendon repair

Lateral epicondylitis repair  
 Biceps tendon reattachment

### **Helicoil Anchor**

Shoulder:  
 Rotator Cuff Repairs  
 Bankart Repair  
 SLAP Lesion Repair  
 Biceps Tenodesis  
 Acromio-Clavicular Separation Repair  
 Deltoid Repair  
 Capsular Shift or Capsulolabral Reconstruction  
 Knee:  
 Medial collateral ligament repair  
 Lateral collateral ligament repair  
 Posterior oblique ligament repair  
 Iliotibial band tenodesis  
 Patellar realignment and tendon repairs  
 Hip:  
 Gluteal tendon repairs  
 - Gluteus medius and gluteus minimus repair

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

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

### **Pile Anchor**

Shoulder:  
 Rotator Cuff Repair  
 Bankart Repair  
 SLAP Lesion Repair  
 Biceps Tenodesis  
 AcromioClavicular Separation Repair  
 Deltoid Repair  
 Capsular Shift or Capsulolabral Reconstruction  
 Knee:  
 Medial Collateral Ligament Repair  
 Lateral Collateral Ligament Repair  
 Patellar Tendon Repair  
 Posterior Oblique Ligament Repair  
 Iliotibial Band Tenodesis  
 Hand/Wrist:

Foot/Ankle:  
 Lateral Stabilization  
 Medial Stabilization  
 Achilles Tendon Repair  
 Metatarsal Ligament Repair/Tendon Repair  
 Hallux Valgus Reconstruction  
 Mid-foot Reconstruction  
 Bunionectomy

Elbow:  
 Biceps Tendon Reattachment  
 Tennis Elbow Repair  
 Ulnar or Radial Collateral Ligament Reconstruction  
 Lateral Epicondylitis Repair  
 Hip:

Scapholunate Ligament Reconstruction    Acetabular Labral Repair  
Ulnar or Radial Collateral Ligament  
Reconstruction

## **6.COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The subject Crius PEEK Suture Anchor System has the same intended use, design features, materials, and sterilization methods as the identified predicate devices. Any technological differences between the subject and predicate devices are considered minor and do not raise different types of questions concerning safety and effectiveness.

## **7.PERFORMANCE DATA**

Performance testing was conducted in accordance with ASTM F543-17, ASTM F1839-08, and the FDA Guidance '*Bone Anchors - Premarket Notification (510(k)) Submissions*' (Issued on March 3, 2020) between the subject device and predicate device. Specifically, the following tests were performed: insertion force testing, insertion torque testing, torsional strength testing, pullout strength testing, and fatigue strength testing. Acceptance criteria were based on similar sized predicate suture anchor devices and the results of the performance testing showed the subject device to have substantially equivalent performance compared to the predicate device. The subject devices meet the pyrogen limit specification (<20 EU/device).

## **8.CONCLUSION**

The Crius PEEK Suture Anchor System is substantially equivalent to the predicate devices. Any differences between the subject device and the predicate devices do not raise questions concerning safety and effectiveness. Based on the indications for use and technological characteristics, it is determined that the proposed device is substantially equivalent to the currently marketed predicate devices.