May 27, 2026

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

Re: K253130
Trade/Device Name: Dione PEEK Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 18, 2026
Received: May 18, 2026

Dear Haifeng 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253130

Please provide the device trade name(s).

Dione PEEK Screw System

Please provide your Indications for Use below.

The Dione PEEK Screw System is indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

K253130

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR §807.92.

1. Date of Preparation:

2. Sponsor Identification

Contact Person: Haifeng Liu

Position: RA Manager

Telephone:+86-15210058659

Email:hfliu@decansmd.com

3. Identification of Subject Device

Trade Name: Dione PEEK Screw System

Common Name:Fastener,Fixation,Nondegradable, Soft Tissue

Regulatory Information

Classification Name: Smooth or threaded metallic bone fixation fastener

Classification: II

Product Code: MBI

Regulation Number: 21 CFR 888.3040

Review Panel: Orthopedic

4. Predicate Devices

The identification of predicates within this submission is as follows:

- Arthrex Tibial GraftBolt System (K103060) - Primary Predicate Device
- Biosure PK Interference Screw (K083635) - Additional Predicate Device
- Gemini Medical Cage System (K242267) - Reference Device
- Gemini Cervical Fusion Cage System (K242195) - Reference Device

5. Indications for Use

The Dione PEEK Screw System is indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee.

6. Device Description

The Dione PEEK Screw System is an intra-tunnel device used to secure soft tissue grafts to bone during cruciate ligament reconstruction procedures. The Dione PEEK Screw System is manufactured from a biocompatible PEEK polymer. The Dione PEEK Screw System consists of various shapes and sizes of screws and cannulas. The RapidFix Screw (ECA011, ECA012) are of conical design and can be used individually. Among them, only the RapidFix Screw (ECA011) can be used in conjunction with the Swell Sheath (ECA021). Product specifications: RapidFix Screw (ECA011): 6×23, 7×28, 8×28, 9×28; RapidFix Screw (ECA012): 6×25, 7×25, 8×25, 9×25; Swell Sheath (ECA021): 7×25, 8×29.5, 9×29.5, 10×29.5. Compatibility relationship: 6 × 23 RapidFix Screw (ECA011) is compatible with 7 × 25 Swell Sheath(ECA021), 7×28 RapidFix Screw (ECA011) is compatible with 8×29.5 Swell Sheath (ECA021), 8×28 RapidFix Screw (ECA011) is compatible with 9×29.5 Swell Sheath (ECA021), 9 × 28 RapidFix Screw (ECA011) is compatible with 10 × 29.5 Swell Sheath (ECA021). Whether used individually or in combination, the function is to squeeze the tendon and ligament grafts into the bone tunnel, thereby achieving the fixation of the grafts.. The device is provided sterile, for single use only.

7. Comparison of Technological Characteristics

The Dione PEEK Screw System consists of RapidFix Screw (ECA011, ECA012), andSwell Sheath (ECA021) . The primary predicate device is the Arthrex Tibial GraftBolt (K103060). The Arthrex Tibial GraftBolt consists of a pre-packaged mating sheath and a screw pair of similar dimensions and geometry, and is made of PEEK. The Biosure PK Interference Screw (K083635) was selected as an additional predicate device as this device has similar technological characteristics to the subject device's RapidFix Screw (ECA012) component. Both screws are made of PEEK and offered in similar dimensions. The Smith & Nephew Biosure PK Interference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. The subject and predicate devices share the same specification and size, indications for use and technological characteristics.

8. Non-Clinical Test Conclusion

The following test standards were utilized to conduct non-clinical testing to support substantial equivalence of the subject device.This included insertion torque,torsional strength,static pullout,and fatigue pullout.Testing compared to predicates.

1. ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws;
2. ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity;
3. ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity;
4. ISO 10993-6:2016 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation;
5. ASTM F2026-23 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications;
6. ISO 11137 - 1:2006 Sterilization of health - care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices;
7. ISO 11137-2:2013 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose;
8. ISO 11137-3:2017 Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control;
9. ISO 11737-1:2018 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products;
10. ISO 11737-2:1998 Sterilization of medical devices—Microbiological methods— Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process;
11. ASTM D4169 - 16 Standard Practice for Performance Testing of Shipping Containers and Systems;
12. ASTM F88/F88M-23 Standard test method for seal strength of flexible barrier materials;
13. ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;

14. ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws.

8. Clinical Test Conclusion

No clinical trials were conducted.

9. Conclusion

The nonclinical performance data submitted in the documents demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device. Based on the information provided in this premarket notification, ZheJiang Decans Medical Devices Co., Ltd. has demonstrated that the proposed Dione PEEK Screw System are substantially equivalent to currently marketed predicates Arthrex Tibial GraftBolt (K103060), and Biosure PK Interference Screw (K083635).