



June 12, 2025

Jeil Medical Corporation
Dajung Lee
RA Specialist
702, 703, 704, 705, 706, 804, 805, 807, 812, 815-ho
55, Digital-ro 34-gil, Guro-gu
Seoul, 08378
South Korea

Re: K243973
Trade/Device Name: FIX-L PEEK PLIF and T-PLIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 23, 2024
Received: December 23, 2024

Dear Dajung Lee:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Brent Showalter -S

Brent Showalter, Ph.D.

Assistant Director

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K243973

Device Name
FIX-L PEEK PLIF and T-PLIF System

Indications for Use (Describe)

FIX-L PEEK PLIF and T-PLIF System is an intervertebral body fusion devices intended for use to skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with up to Grade 1 Spondylolisthesis at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. FIX-L PEEK PLIF and T-PLIF System is indicated to be used with autologous bone graft to facilitate fusion and are intended to be used with supplemental fixation. The device is to be used in patients who have had six months of nonoperative treatment.

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.

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510(K) Summary

1. Date Prepared [21 CFR 807.92(a)(a)]

December 23, 2024

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: Jeil Medical Corporation
 - Address: 702•703•704•705•706•707•804•805•807•812•815-ho, 55, Digital-ro 34-gil, Guro-gu, Seoul, 08378, Republic of Korea

- Contact Name: Dajung Lee / RA Specialist
 - Telephone No. +82 2 850 3991
 - Fax No. +82 2 850 3536
 - Email Address: dajunglee@jeilmed.co.kr

- Registration Number: 3004049923

- Name of Manufacturer: Same as Sponsor
 - Address: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name; FIX-L PEEK PLIF and T-PLIF System
- Common Name; Rod, Fixation, Intramedullary And Accessories
- Classification Name; Intervertebral fusion device with bone graft, lumbar
- Classification Panel; Orthopedic
- Classification Regulation; 21 CFR 888.3080
- Product Code; MAX
- Device Class; II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The legally marketed device(s) to which substantial equivalence is claimed is/are:

Primary Predicate Device	K190563 - 4CIS® PEEK PLIF Cage, Solco Biomedical Co., Ltd.
Reference Device	K212266 - FIX-C PEEK Anterior Cervical Interbody System, Jeil Medical Corporation

There are no significant differences between the subject device and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in intended use and technological characteristics as internal fixation components.

5. Description of the Device [21 CFR 807.92(a)(4)]

FIX-L PEEK PLIF and T-PLIF System intended for use as an interbody fusion cage device and must be used with supplemental fixation. The device is available in a variety of different sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The configurations are designed pursuant to a specific surgical approach and consist of the following: 1) Posterior Lumbar Approach (PLIF) and 2) Transforaminal Posterior Lumbar Approach (T-PLIF). FIX-L PEEK PLIF and T-PLIF System is made of PEEK VESTAKEEP i4R body (ASTM F2026) and tantalum markers (ASTM F560) for ease of visualization on radiographs. FIX-L PEEK PLIF and T-PLIF System is a non-sterile device, and it is required to be sterilized via autoclave method by the hospital prior to surgery.

6. Indications for use [21 CFR 807.92(a)(5)]

FIX-L PEEK PLIF and T-PLIF System is an intervertebral body fusion devices intended for use to skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with up to Grade 1 Spondylolisthesis at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. FIX-L PEEK PLIF and T-PLIF System is indicated to be used with autologous bone graft to facilitate fusion and are intended to be used with supplemental fixation. The device is to be used in patients who have had six months of nonoperative treatment.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Based on the technological feature comparison, the subject device was found that there are no significant differences between the subject device and predicate devices that would adversely affect the use of the product and it is substantially equivalent to predicate device in technological characteristics.

Non-Clinical Test Summary:

Bench tests were conducted to ensure the safety and effectiveness of the device as well as to demonstrate substantial equivalence to the predicate device. The test results demonstrated that the subject device complies with the following standards:

- ASTM F2077, Standard Test Methods for Intervertebral Body Fusion Devices
 - Static and Dynamic Axial Compression Testing
 - Static and Dynamic Compression Shear Testing

- ASTM 2267, Standard Test Method for Measuring Load-Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
 - Subsidence Testing

The results of this testing indicate that the FIX-L PEEK PLIF and T-PLIF System is equivalent to the predicate device.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

Based on the submitted information in this premarket notification, the subject device is substantially equivalent to the predicate device in terms of:

- Intended use
- Technological characteristics (Human Factor, Shape, Design, Materials, Sterilization Method, Biocompatibility and Performance)

The subject device has met the performance, safety, and effectiveness of the device for its intended use.

9. Conclusion [21 CFR 807.92(b)(3)]

In all respects, the FIX-L PEEK PLIF and T-PLIF System is substantially equivalent to the legally marketed device. Above all, the subject device has equivalent intended use and technological characteristics. Further, nonclinical verification and validation to determine substantial equivalence provide additional evidence that subject device is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.