June 27, 2025

Jeil Medical Corporation
Jinwoo Kim
RA Specialist
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55, Digital-ro 34-gil, Guro-gu
Seoul, 08378
South Korea

Re: K251431
Trade/Device Name: FIX-C PEEK ACIF SA System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: May 8, 2025
Received: May 8, 2025

Dear Jinwoo Kim:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251431

Device Name
FIX-C PEEK ACIF SA System

Indications for Use *(Describe)*
The FIX-C PEEK ACIF SA System consists of a stand-alone interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The stand-alone interbody cages must be used with internal screw fixation. The FIX-C PEEK ACIF SA System is also required to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

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) #:

510(k) Summary

Prepared on: 2025-05-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Jeil Medical Corporation
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Applicant Contact Telephone	+82 2 850 3934
Applicant Contact	Ms. Jinwoo Kim
Applicant Contact Email	jinwookim@jeilmed.co.kr

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FIX-C PEEK ACIF SA System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Integrated Fixation, Cervical
Regulation Number	888.3080
Product Code(s)	OVE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192502	Divergence™ Anterior Cervical Fusion System (For Stand-Alone Interbody Device Only)	OVE
K212266	FIX-C PEEK Anterior Cervical Interbody System	ODP
K231251	FlexWing Anterior Cervical Plate System	KWQ

Device Description Summary

21 CFR 807.92(a)(4)

The FIX-C PEEK ACIF SA System consists of a stand-alone interbody fusion device with internal screw fixation. The FIX-C PEEK ACIF SA System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc.

The FIX-C PEEK ACIF SA System is comprised of a PEEK interbody cage and screws. The PEEK interbody cage is made from medical-grade polyetheretherketone (PEEK) which is radiolucent and contains radiopaque titanium clips made from medical-grade titanium alloys. The titanium clip assembled in the PEEK cage includes a Zero-Step Mechanism designed to prevent the screw from disengaging or loosening from the cage. The PEEK materials conform to ASTM F2026, and the titanium alloys materials conform to ASTM F136.

The FIX-C PEEK ACIF SA System is provided non-sterile. The devices must be sterilized prior to use per ISO 17665-1.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The FIX-C PEEK ACIF SA System consists of a stand-alone interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral

endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The stand-alone interbody cages must be used with internal screw fixation. The FIX-C PEEK ACIF SA System is also required to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Indications for Use Comparison 21 CFR 807.92(a)(5)

There are no differences of Indications for Use between the subject device and the predicate device (K192502).

Technological Comparison 21 CFR 807.92(a)(6)

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

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The subject device and predicate device are stand-alone interbody devices that must be used with internal screw fixation. They are used in the anterior cervical interbody fusion (ACIF) procedures. Detailed design/dimension would not be the same, but equivalent.

Bench tests were conducted to demonstrate substantial equivalence to the predicate device. The tests were conducted according to the following standards:

• ASTM F2077, Standard Test Methods for Intervertebral Body Fusion Devices
- Static axial compression test
- Static compression-shear test
- Static torsion test
- Dynamic axial compression test
- Dynamic compression-shear test
- Dynamic torsion test

• ASTM F2267, Standard Test Method for Measuring Load-Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
- Subsidence test

Clinical data is not applicable.

Bench tests were conducted for the subject device according to ASTM F2077 and ASTM F2267. All test results were higher than the acceptance criteria from the reference literature. Therefore, substantially equivalent mechanical performance with the predicate device has been demonstrated.

Based on the indications for use, technological characteristics, bench testing, and comparison with the predicate device, the subject device has demonstrated substantial equivalence for its intended use.