



February 18, 2025

Jeil Medical Corporation
Jinwoo Kim
RA Specialist
702•703•704•705•706•707•804•805•807•812•815-ho, 55,
Digital-ro 34-gil, Guro-gu
Seoul, South Korea

Re: K243915
Trade/Device Name: FIX-C 3D Ti ACIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 20, 2024
Received: December 20, 2024

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

Indications for Use

Submission Number (if known)

K243915

Device Name

FIX-C 3D Ti ACIF System

Indications for Use (Describe)

The FIX-C 3D Ti ACIF System is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at one or multiple contiguous levels from C2-T1.

The FIX-C 3D Ti ACIF System is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. These patients should have had at least six weeks of nonoperative treatment. The FIX-C 3D Ti ACIF System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Jeil Medical Corporation
Applicant Address	702•703•704•705•706•707•804•805•807•812•815-ho, 55, Digital-ro 34-gil, Guro-gu Seoul 08378 Korea, South
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 3D Ti ACIF System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
Regulation Number	888.3080
Product Code(s)	ODP

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233839	Peridot-PT Anterior Cervical Intervertebral body fusion System	ODP
K241738	PYXIS 3D Titanium Cervical Cage System	ODP
K212266	FIX-C PEEK Anterior Cervical Interbody System	ODP

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The FIX-C 3D Ti ACIF System comprises of 3D-printed porous titanium spinal cages intended to stabilize the spinal segment, restore intervertebral height, and facilitate interbody fusion in the cervical. The spinal cages are used in the anterior cervical interbody fusion (ACIF) procedures. The devices are intended to be used with supplemental spinal fixation (e.g., using anterior plate system).

The spinal cages are made from Ti-6Al-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the spinal cages allows them to be packed with autogenous bone graft comprised of cancellous and/or corticocancellous bone graft.

The FIX-C 3D Ti ACIF System is manufactured in a pre-designated standard size, not patient-matched. The spinal cages are available in various sizes, footprints, heights, and angles.

The FIX-C 3D Ti ACIF 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 3D Ti ACIF System is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy,

myelopathy, and/or pain at one or multiple contiguous levels from C2-T1.

The FIX-C 3D Ti ACIF System is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. These patients should have had at least six weeks of nonoperative treatment. The FIX-C 3D Ti ACIF System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

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 (K233839).

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 3D-printed porous titanium spinal cages. The spinal cages 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.