December 21, 2021

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
Korea

Re: K212266
Trade/Device Name: FIX-C PEEK Anterior Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: November 19, 2021
Received: November 23, 2021

Dear Mr. 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for
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)*
K212266

Device Name
FIX-C PEEK Anterior Cervical Interbody System

Indications for Use *(Describe)*
The FIX-C PEEK Anterior Cervical Interbody System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the FIX-C PEEK Anterior Cervical Interbody System should be packed with autogenous bone graft and implanted via an anterior approach. The FIX-C PEEK Anterior Cervical Interbody System is intended to be used with supplemental fixation.

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.

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510(k) Summary

[As required by 21 CRF 807.92]

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

19th November 2021

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

- Name of Sponsor: Jeil Medical Corporation
  - Address: 702,703,704,705,706,804,805,807,812,815-ho, 55, Digital-ro 34-gil, Guro-gu, Seoul, 08378, Korea
- Contact Name: Dajung Lee / RA Specialist
  - Telephone No.: +82 2 850 3591
  - 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-C PEEK Anterior Cervical Interbody System
- Common Name; Intervertebral Body Fusion Device
- Classification Name; Intervertebral Fusion Device with Bone Graft, Cervical
- Classification Panel; Orthopedic
- Classification regulation; 21 CFR 888.3080
- Product code; ODP
- Device Class; II

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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:

Predicate Device	K120275 – SYNTHES ACIS/VERTEBRAL SPACER CR, SYNTHES (USA) LLC
Reference Device	K181806 – ARIX Sternal System, Jeil Medical Corporation

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

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

The FIX-C PEEK Anterior Cervical Interbody System intended for use as an interbody fusion cage device and must be used with supplemental fixation. The devices are available in a variety of different sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The FIX-C PEEK Anterior Cervical Interbody System devices are designed for an anterior approach.

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

The FIX-C PEEK Anterior Cervical Interbody System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the FIX-C PEEK Anterior Cervical Interbody System should be packed with autogenous bone graft and implanted via an anterior approach. The FIX-C PEEK Anterior Cervical Interbody System is intended to be used with supplemental fixation.

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

Based on the technological feature comparison in below table, the subject device was found that there are no significant differences between the subject device and predicate device (K120275) that would adversely affect the use of the product and it is substantially equivalent to predicate device in technological characteristics.

Parameter	Conclusion
Design/shape	Equivalent
Depth*Width	Equivalent
Height	Equivalent
Bone Graft Contact Area	Similar
Materials (PEEK and Ti-6AL-4V ELI)	Equivalent
Sterilization (Moist Heat or Gamma)	Similar
Biocompatibility	Equivalent
Performance (ASTM F2077 and ASTM F2267) - *Static and Dynamic Torsion Testing* - *Static and Dynamic Axial Compression Testing* - *Static and Dynamic Compression Shear Testing* - *Subsidence Testing*	Equivalent

S.E.	<u>Similarities</u> The subject device has equivalent design features, material, sterilization method, biocompatibility and performance features compared to the predicate device (K120275). <u>Differences</u> User Moist Heat Sterilization validation was conducted for non-sterile product, and it was confirmed the S.A.L. (Sterility Assurance Level), 10^{-6} and ensure the effectiveness. As for the the bone graft contact area, the subject device had larger than or similar value to the predicate device. Other than this, there were no significant differences between subject device and predicate device.

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 (K120275) in terms of:

- Intended use
- Technological characteristics (Design features, Material, Sterilization methods, 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-C PEEK Anterior Cervical Interbody System is substantially equivalent to the legally marketed device (K120275). 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.