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

July 24, 2024

Re: K231251
Trade/Device Name: FlexWing Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: July 19, 2024
Received: July 19, 2024

Dear Sejin Ryu:

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.

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.07.24 11:53:40 -04'00'

for

Colin O'Neill, M.B.E
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K231251

Device Name

FlexWing Anterior Cervical Plate System

Indications for Use *(Describe)*

The FlexWing Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine(C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

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 CFR 807.92]

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

July 19, 2024

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, Republic of Korea
- Contact Name: Sejin Ryu / RA Manager
  - Telephone No.: +82 2 850 3583
  - Fax No.: +82 2 850 3536
  - Email Address: rsj@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;	FlexWing Anterior Cervical Plate System
Common Name;	Anterior Cervical Plate System
Classification Name;	Spinal Intervertebral Body Fixation Orthosis
Classification Panel;	Orthopedic
Classification Regulation;	21 CFR 888.3060
Product Code;	KWQ
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	K192314 – RESONATE™ Anterior Cervical Plate System, Globus Medical Inc
Additional Predicate	K030866 – Synthes Anterior CSLP System, SYNTHES
Reference Device	K180972 – ARIX Clavicle 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 design, function, materials, and operational principles as anterior cervical plate system.

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

The FlexWing Anterior Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1.
The FlexWing Anterior Cervical Plate System is made of Titanium Alloy (Ti-6AL-4V) and Nickel-Titanium Alloy, which meet ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI(Extra Low Interstitial) Alloy for Surgical Implant Applications, and ASTM F2063, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants. The Anterior Cervical Plates consist of 1 to 3 levels which have different lengths. The bone screws are 3.5 and 4.0mm in diameter with self-tapping and self-drilling threads and provided in lengths from 10.0 to 26.0mm.

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

The FlexWing Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

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

The rationale for substantial equivalence is based on consideration of the following characteristics:

Regulatory Classification: Same as the predicate devices
Indications for Use: Substantially equivalent (SE) to the predicate devices
Materials: Substantially equivalent (SE) to the predicate devices
Design Features: Substantially equivalent (SE) to the predicate devices

Non-Clinical Test Summary:
The following tests were performed per ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model on Anterior Cervical Spine Plate System to demonstrate substantial equivalence of the subject device.

- Static Compression Bending
- Static Torsion
- Compression Bending Fatigue

Additionally, screw pushout testing and ASTM F2129 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices were performed to demonstrate substantial equivalence of the subject device.

Clinical Test Summary:
No clinical studies were considered necessary and performed.

8. Substantial Equivalence [21 CFR 807.92(b)(3)]

When compared to the predicate device (K140234, K030866), the FlexWing Anterior Cervical Plate System presented in this submission has similar:

- Indications for Use
- Technological characteristics
- Function
- Design features
- Performance
- Biocompatibility
- Method of sterilization.

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

The information provided within this premarket notification demonstrates that proposed device is determined to be substantially equivalent (SE) to the predicate devices.