June 28, 2024

ARTFX MEDICAL LLC
Ms. Gizem Boz
Quality Manager
50 N Laura St. 25th Floor
Jacksonville, Florida 32202

Re: K240893
Trade/Device Name: ARTFX MEDICAL Cervical PEEK Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 18, 2024
Received: April 1, 2024

Dear Ms. Boz:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240893

Device Name

ARTFX MEDICAL Cervical PEEK Cages

Indications for Use *(Describe)*

ARTFX MEDICAL Cervical PEEK Cages are made to be implanted into the appropriate vertebral section to help provide stability for spinal fusion after a diseased cervical disc producing neck and/or arm pain is removed during spinal decompression for patients who have had six weeks of non-operative treatment.

Cervical PEEK Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.

Cervical PEEK Cages facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and packed with autogenous bone. ARTFX MEDICAL Cervical PEEK Cages are 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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Section 3

510(k) Summary

(as required by 21 CFR 807.92)

3.1 Owner/Submitter Information

Owner: ARTFX MEDICAL LLC

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Phone: +1 917 445 2085

Fax: -

Contact Person: OZGEN OZFIDAN

E-mail: ozgen@artfxmed.com

ESTABLISHMENT REGISTRATION: 3017435639

3.2 Device Information

Common Name: Intervertebral Body Fusion

Device

Trade Name: ARTFX MEDICAL Cervical PEEK Cages

Classification name: Intervertebral body fusion device (21 CFR 888.3080)

Device Panel: Orthopedic

Product codes: ODP, OVE

Proposed Class: II

PREDICATE DEVICES:

	Primary Predicate	Additional Predicate
510(k) Number	K212266	K212358
Manufacturer	Jeil Medical Corporation	SpineUp Inc.
Trade Name	FIX-C PEEK Anterior Cervical Interbody System	Romero Cervical Cage

3.3 Substantial Equivalence

The proposed devices are substantially equivalent to Jeil Medical Corporation (K212266) for cervical peek cages and Spine Up Inc (K212358). These devices have the same intended use, technological characteristics, and basic design as the proposed device.

For Jeil Medical Corporation, FIX-C PEEK Anterior Cervical Interbody System implants are made from medical grade polyetheretherketone (PEEK) per ASTM F2026 with a titanium posterior insert marker pin and two radiographic marker pins (Ti -6Al-4V ELI) per ASTM F136.

The Romero Cervical Cage is an anterior cervical interbody device consisting of a PEEK HA or PEEK-OPTIMA interbody cage with tantalum radiographic markers and two Titanium (Ti -6Al-4V ELI) fixation screws for cages with screw holes. The PEEK material used conforms to ASTM F2026, the Titanium screws conform to ASTM F136, and the Tantalum radiographic markers conform to ASTM F560.

3.4 Device Description

"Cervical Peek Cage" refers to a type of intervertebral cage used in spine surgery in the cervical (neck) region. ARTFX Cervical Cages cervical intervertebral devices made from PEEK Optima (per ASTM F2026) are created to be implanted into appropriate vertebral sections to help provide stability for spinal fusion after a diseased cervical disc-producing neck and/or arm pain is removed during spinal decompression for patients who have had six weeks of non-operative treatment. Cervical peek cages are often used in spinal fusion surgeries.

Fusion surgeries are designed to fuse two vertebrae.

The single-use implant devices feature an open cavity in the interior geometry to accommodate autogenous bone graft and maximize bone growth, with anti-migration teeth to engage the vertebral end plates and prevent expulsion.

The ARTFX Cervical Cages are supplied sterile, single-use, and are fabricated from PEEK that conforms to ASTM F2026 for cages, and with markers and pins that are titanium alloy (Ti6Al4V-ELI) that conforms to ASTM F136.

ARTFX En Vivo Spinal Cervical Peek Cage has a peek cage body.
Components of the ARTFX En Vivo Spinal cage have two pins, which assist in the positive anchorage of the implant between the superior and inferior vertebral bodies, and three radiographic markers.

ARTFX Simplex Spinal XI Cervical Locking Peek Cage has a peek cage body. Components of ARTFX Simplex Spinal XI Cervical Locking Peek Cage has two titanium screws which the system is attached to the cervical spine and a titanium locking screw.

Cervical cages consist of 3 models: En Vivo Anatomical Surface, En Vivo Straight Structure, and Simplex.

3.5 Indications for Use

ARTFX MEDICAL Cervical PEEK Cages are made to be implanted into the appropriate vertebral section to help provide stability for spinal fusion after a diseased cervical disc producing neck and/or arm pain is removed during spinal decompression for patients who have had six weeks of non-operative treatment.

Cervical PEEK Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.

Cervical PEEK Cages facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and packed with autogenous bone. ARTFX MEDICAL Cervical PEEK Cages are to be used with supplemental fixation.

3.6 Technical Comparison

The summary of the technological characteristics of The Proposed Device compared to the predicate devices is as follows:

3.6.1 Material

The Romero Cervical Cage is an anterior cervical interbody device consisting of a PEEK HA or PEEK-OPTIMA interbody cage with tantalum radiographic markers and two Titanium (Ti -6Al-4V ELI) fixation screws for cages with screw holes. The PEEK material used conforms to ASTM F2026, the Titanium screws conform to ASTM F136, and the Tantalum radiographic markers conform to ASTM F560.

For Jeil Medical Corporation, FIX-C PEEK Anterior Cervical Interbody System implants are made from medical grade polyetheretherketone (PEEK) per ASTM F2026 with a titanium posterior insert marker pin and two radiographic marker pins (Ti -6Al-4V ELI) per ASTM F136.

They change in size.

3.6.2 Design

The Proposed and Predicate Devices have similarly designed but different-sized peek cages for Cervical Peek Cages. The design incorporates features similar to the predicate with similar footprints and heights to create a complete range of sizes for the surgeon. The Simplex system is attached to the cervical spine using titanium screws.

3.6.3 Function

The Proposed and Predicate Devices have the same function, which helps provide stability for spinal fusion and is designed to fuse two vertebrae. These cages stimulate bone growth and allow the vertebrae to fuse.

3.7 Conclusion:

ARTFX SPINAL CERVICAL PEEK CAGES have similar technological characteristics as predicate devices, including the materials, design, function, range of sizes, manufacturing processes, surgical techniques, and intended use. The minor differences in design and sizing options present only some safety and effectiveness issues.

The intended use and material of the subject ARTFX SPINAL CERVICAL PEEK CAGES are identical to those of the predicate devices.

Non-clinical testing including subsidence per ASTM F2267 and static and dynamic axial compression, compression-shear, and torsion per ASTM F2077 was conducted. The results showed that the performance of the proposed devices is substantially equivalent.