October 2, 2024

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

Re: K240889
Trade/Device Name: ARTFX Lumbar PEEK Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 4, 2024
Received: September 4, 2024

Dear Gizem 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.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240889

Device Name

ARTFX Lumbar PEEK Cages

Indications for Use *(Describe)*

The ARTFX Lumbar PEEK Cages are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment.

The devices are designed to be used with supplemental fixation and autograft/autologous bone grafts to facilitate fusion for each spinal region.

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.

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"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."

Section 3

510(k) Summary

(as required by 21 CFR 807.92)

3.1 Owner/Submitter Information

Owner: ARTFX MEDICAL LLC

Address: 50 LAURA ST N 25TH FLOOR, JACKSONVILLE, FL, 32202 USA

Phone: +1 917 445 2085

Fax: -

Contact Person: OZGEN OZFIDAN

E-mail: ozgen@artfxmed.com

ESTABLISHMENT REGISTRATION: 3017435639

3.2 Device Information

Common Name: Interbody Fusion Cages

Trade Name: ARTFX Lumbar PEEK Cages

Classification name: Regulation description: Intervertebral Fusion Device With Bone Graft, Lumbar (21 CFR 888.3080)

Device Panel: Orthopedic

Product codes: MAX

Proposed Class: II

PREDICATE DEVICE:

	Primary Predicate	Additional Predicate
510(k) Number	K152011	K180078
Manufacturer	Spinal Elements, Incorporated	Innovasis, Inc.
Trade Name	Lucent® Intervertebral Body Fusion Device	Px® PEEK IBF System, Px HA® PEEK IBF System, TxHA™ PEEK IBF System

3.3 *Substantial Equivalence*

The proposed device is substantially equivalent to the devices from Spinal Elements, Incorporated (K152011) and Innovasis, Inc. (K180078). These devices have the same intended use, technological characteristics, and basic design as the proposed device. The only differences are to geometry/sizes.

3.4 *Device Description*

The ARTFX Lumbar PEEK Cages consist of 3 different models: TLIF, PLIF and Expandable PLIF. The System implants are supplied sterile, for single use and are fabricated from PEEK Optima that conforms to ASTM F2026. Various sizes of these components are available.

The Lumbar Cages are lumbar intervertebral devices to be implanted into the appropriate lumbar vertebral section to help provide stability for spinal fusion after a diseased lumbar disc producing back pain is removed during spinal decompression.

ARTFX Lumbar PEEK Cages feature an open cavity to accommodate autogenous bone graft and provide stability for fusion. The height of the Expandable PLIF device, can be increased by up to 2 mm due to the expandable structure. Also, sharp teeth on the implant's surface engage the vertebral endplates to prevent cage migration.

3.5 *Indications for Use*

The ARTFX Lumbar PEEK Cages are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment.

The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.

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 Proposed and Predicate Devices are fabricated of the same material, which is Invibio PEEK-OPTIMA that conforms to ASTM F2026.

3.6.2 Design

The Proposed and Projected Device have similarly designed and have the same attachment mechanism but different dimensions. The design incorporates the same design features as the previous model with similar footprints and heights to create a complete range of sizes for the surgeon..

3.6.3 Function

The Proposed and Predicate Devices have the same function, which is acting as a spinal implant construct to stabilize and promote spinal fusion.

Conclusion

ARTFX Lumbar PEEK Cages similar technological characteristics as the 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 do not present new issues of safety and effectiveness.

The intended use and material of the subject ARTFX Lumbar PEEK Cages are identical to this of the predicate devices.

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