October 6, 2022

ARFTX Medical LLC
Ozgen Ozfidan
CEO
50 Laura Street #2524
Jacksonville, Florida 32202

Re: K211892
Trade/Device Name: ArtFx Corpectomy Cages (Espinax and Distractania Corpectomy Cages)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: September 6, 2022
Received: September 7, 2022

Dear Ozgen Ozfidan:

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,

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)*
K211892

Device Name
ArtFx Corpectomy Cages (ESPINAX and DISTRACTANIA CORPECTOMY CAGES)

Indications for Use *(Describe)*
The ESPINAX CORPECTOMY CAGE is intended for use in skeletally mature patients in the cervical spine (C2-T1) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The DISTRACTANIA CORPECTOMY CAGE is intended for use in skeletally mature patients in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The ESPINAX and DISTRACTANIA CORPECTOMY CAGES are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The ESPINAX and DISTRACTANIA CORPECTOMY CAGES are intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material is optional.

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.

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510(K) SUMMARY

Contact

Person/Applicant:

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PHONE: +1 917 445 2085

FAX: -

EMAIL: ozgen@ARTFXmed.com

ESTABLISHMENT REGISTRATION: 3017435639

DEVICE IDENTIFICATION:

TRADE NAME: ARTFX CORPECTOMY CAGES (ESPINAX and DISTRACTANIA CORPECTOMY CAGES)

CLASSIFICATION NAME: APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY

REGULATION NUMBER:

888.3060 **REVIEW PANEL:**

ORTHOPEDIC **PRODUCT CODE:**

MQP,PLR

REASON FOR SUBMISSION: NEW DEVICE

FDA GUIDANCE DOCUMENTS: Guidance for Industry and FDA Staff Spinal System 510(k)s

INDICATIONS FOR USE:

The ESPINAX CORPECTOMY CAGE is intended for use in skeletally mature patients in the cervical spine (C2-T1) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The DISTRACTANIA CORPECTOMY CAGE is intended for use in skeletally mature patients in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The ESPINAX and DISTRACTANIA CORPECTOMY CAGES are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage

tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The ESPINAX and DISTRACTANIA CORPECTOMY CAGES is are intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material is optional.

DEVICE DESCRIPTION:

The ARTFX CORPECTOMY CAGE includes product range for cervical and lomber applications.

ESPINAX SPINAL CERVICAL CORPECTOMY CAGE ESPINAX SPINAL CERVICAL CORPECTOMY CAGE-ANGLED	used in cervical spine (C2- T1)
DISRACTANIA SPINAL LUMBAR CORPECTOMY CAGE DISRACTANIA SPINAL LUMBAR CORPECTOMY CAGE-ANGLED	used in lumber spine (T1-L5)

ESPINAX SPINAL CERVICAL CORPECTOMY CAGE is used in cervical spine (C2- T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

DISRACTANIA SPINAL LUMBAR CORPECTOMY CAGE is used , in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

ARTFX CORPECTOMY CAGE consisting of two parts, can easily be placed between the vertebra are the features to be distraction. Product is available in the cervical and lumbar spine, the upper and lower vertebrae, providing one to one contact with the angled surface. With gear structure with full contact surfaces of vertebrae forming the product surface, providing a tighter grip, eliminating the risk of slipping. Distraction prior to grafting, graft area at that provide a locking device which has a single-stage system after distraction.

The ARTFX CORPECTOMY CAGE, vertebral structure is used in cases where a portion or all of the damage. This damages the vertebral structure, tumors, fractures, and infections may occur due to.

The ARTFX CORPECTOMY CAGE is supplied non-sterile, single use and fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to the ISO 5832-2 and ASTM F136 .Various sizes of these components are available.

NON-CLINICAL TESTING:

Non-clinical testing including below tests are performed according to the Guidance for Industry and FDA Staff Spinal System 510(k)s.

- Dynamic Compression Test (ASTM F2077)
- Dynamic Compression Shear Test (ASTM F2077)
- Dynamic Compression Torsion Test(ASTM F2077)
- Static Compression Test (ASTM F2077)
- Static Compression Shear Test (ASTM F2077)
- Static Compression Torsion Test (ASTM F2077)
- Subsidence Test Report(ASTM F2267)
- Expulsion test

PREDICATE DEVICE:

TRADE/ DEVICE NAME: SMALL VBR

REGULATION NUMBER: 21 CFR 888.3060

REGULATION NAME: SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS

REGULATORY CLASS: Class II

PRODUCT CODE: MQP, PLR

510(K) NUMBER: K192117

CONCLUSION:

The ARTFX CORPECTOMY CAGE has the same intended use and technological characteristics as the predicate device. Therefore, the ARTFX CORPECTOMY CAGE is substantially equivalent for its intended use.