April 20, 2023

ArtFX Medical LLC
Ozgen Ozfidan
CEO
50 Laura St. N., 25th Floor
Jacksonville, Florida 32202

Re: K212220
Trade/Device Name: ArtFX Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: March 16, 2023
Received: March 24, 2023

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,

Colin O'neill -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212220

Device Name
ARTFX SPINAL FIXATION SYSTEM

Indications for Use *(Describe)*
ARTFX SPINAL FIXATION SYSTEM is intended for use in the noncervical spine. When used as an anterior/ anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the ARTFX SPINAL FIXATION SYSTEM is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:
-Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
-Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
-Spinal stenosis;
-Curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- Tumor;
-Pseudoarthrosis; and Failed previous fusion

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)

Owner/Submitter Information

Owner: ARTFX MEDICAL LLC

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

Phone: +1 917 445 2085

Date Prepared: April 17, 2023

Contact Person: OZGEN OZFIDAN

E-mail : ozgen@artfxmed.com

ESTABLISHMENT REGISTRATION: 3017435639

Device Information

Common Name: Thoracolumbosacral pedicle screw system

Trade Name: ARTFX SPINAL FIXATION SYSTEM

Classification name: Thoracolumbosacral pedicle screw system (21 CFR 888.3070)

Device Panel: Orthopedic

Product codes: NKB,KWQ,KWP

Proposed Class: II

PREDICATE DEVICES:

	Primary Predicate	Additional Predicate	Additional Predicate	Additional Predicate
510(k) Number	K171497	K091445	K994121	K071373
Manufacturer	Mikron Makina Sanayi Ticaret Co. Ltd.	Medtronic Sofamor Danek USA	Synthes	Stryker Spine
Trade Name	Mikron Spinal Fixation System	CD HORIZON Spinal System	USS Small Stature	XIA 3 Spinal System

Substantial Equivalence/Technological Comparison

The proposed devices are substantially equivalent to the devices Mikron Spinal Fixation System (K171497), CD HORIZON Spinal System (K091445), USS Small Stature (K994121) and XIA 3 Spinal System (K071371). These devices has the same intended use, technological characteristics and basic design as the proposed device.

Device Description

The Proposed system is a top-loading multiple component, posterior spinal fixation system consisting of polyaxial pedicle screws, monoaxial pedicle screws, cannulated screws , rods (Straight and pre-bent) , connectors , hooks and setscrews. The Artfx Spinal Fixation System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion.

ARTFX SPINAL FIXATION SYSTEM is supplied non-sterile, single use and fabricated from titanium alloy (Ti6Al4V-ELI) that conforms to ASTM F136.

Indications for Use

ARTFX SPINAL FIXATION SYSTEM is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the ARTFX SPINAL FIXATION SYSTEM is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

-Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);

-Spondylolisthesis;

-Trauma (i.e. fracture or dislocation);

-Spinal stenosis;

-Curvatures (i.e. scoliosis, kyphosis, and/or lordosis)

-Tumor;

-Pseudoarthrosis; and Failed previous fusion

Performance Testing:

Non-clinical testing was performed in accordance with ASTM F1717 (static and dynamic compression bending, static torsion), and ASTM F1798 (axial grip, torsional grip, static flexion-extension). The results demonstrated substantially equivalent mechanical performance of the subject device.

Conclusions:

ArtFX SPINAL FIXATION SYSTEM has 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 SPINAL FIXATION SYSTEM is identical to this of the predicate devices. The information presented demonstrates the substantial equivalence of the subject device.