June 28, 2022

ArtFx Medical LLC
Ozgen Ozfidan
CEO
50 Laura Street North, 25th Floor
Jacksonville, Florida 32202

Re: K211718
Trade/Device Name: Venus Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 10, 2022
Received: June 14, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211718

Device Name
VENUS CERVICAL PLATE SYSTEM

Indications for Use *(Describe)*
The Venus Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with 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
-Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
-Pseudarthrosis
-Failed previous fusion
-Decompression of the spinal cord following total or partial cervical vertebrectomy
-Spondylolisthesis
-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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Contact Person/Applicant:

NAME: OZGEN OZFIDAN

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PHONE: +1 917 445 2085

FAX: -

EMAIL: ozgen@artfxmed.com

ESTABLISHMENT REGISTRATION: 3017435639

DATE : 10.06.2022

DEVICE IDENTIFICATION:

TRADE NAME: VENUS CERVICAL PLATE SYSTEM

DEVICE COMMON NAME:ANTERIOR CERVICAL PALTE

CLASSIFICATION NAME: APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY

REGULATION NUMBER: 888.3060

REVIEW PANEL: ORTHOPEDIC

PRODUCT CODE: KWQ

REASON FOR SUBMISSION: NEW DEVICE

FDA GUIDANCE DOCUMENTS:

INDICATIONS FOR USE:

The Venus Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with 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

-Deformities or curvatures (including kyphosis, lordosis, or scoliosis)

-Pseudarthrosis

-Failed previous fusion

-Decompression of the spinal cord following total or partial cervical vertebrectomy

-Spondylolisthesis

-Spinal stenosis.

DEVICE DESCRIPTION:

The Venus Cervical Plate System is supplied non-sterile, single use and are fabricated from titanium alloy (Ti6Al4V-ELI) that conforms to ASTM F136. Various sizes of these components are available.

The Venus Cervical Plate System configurations ranging in lengths from 17 mm to 25 mm for the one-level plates, 27 mm to 40 mm for the two-level plates, 45 mm to 65 mm for the three-level plates, , and 70 mm to 90 mm for the four -level plates. All of the plate levels incorporate blocking mechanism to aid in prevention of bone screw back-out. The bone screws are provided with fixed angles available in self- tapping design. The fixed bone screws are inserted at a defined angle. The bone screws are offered in 3.5 mm, 4.0 mm and 4.50 mm diameters in lengths of 12 mm – 22 mm. The implants (bone screws and cervical plates) are provided as single-use, non-sterile devices manufactured from implantable grade titanium alloy (TI6Al4V-ELI).

The Venus Cervical Plate System is intended for use as an aid in cervical spinal fusion .

The Venus Cervical Plate System is supplied non-sterile, single use and are fabricated from titanium alloy (Ti6Al4V-ELI) that conforms to ASTM F136. Various sizes of these components are available.

NON-CLINICAL TESTING:

Non-clinical testing including Pull-out Test (ASTM F543-17), Driving Torque Test (ASTM F543-17) Torsion Test (ASTM F543-17), Self-Tapping Test (ASTM F543-17), Fatigue Test (ASTM F1717-18) Static Compression Test (ASTM F1717-18), Static Tensile Test (ASTM F1717-18), and Static Torsion Test (ASTM F1717-18) were conducted. The results showed that the performance of the proposed devices is substantially equivalent.

PREDICATE DEVICE:

TRADE/ DEVICE NAME: STRYKER SPINE NULOCK ANTERIOR CERVICAL PLATING SYSTEM

REGULATION NUMBER: 21 CFR 888.3060

REGULATION NAME: APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY

REGULATORY CLASS: Class II

PRODUCT CODE: KWQ

510(K) NUMBER: K083562

Technological Characteristics, Comparison to Predicate Device

The Venus Cervical Plate 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.

REFERENCE DEVICE:

TRADE/ DEVICE NAME: Mikron Spinal Fixation System

REGULATION NUMBER: 21 CFR 888.3070

REGULATION NAME: THORACOLUMBOSACRAL PEDICLE SCREW SYSTEM

REGULATORY CLASS: Class II

PRODUCT CODE: NKB

510(K) NUMBER: K171497

The 510(K) number of the cleared device is K171497 for ‘’Polyaxial screws and rods’’ under Mikron Makine ,it is refence device for biological evaluation of this submission i

The chemical characterization for raw material and end product of “MSFX – MİKRON SPINAL FIXATION POLYAXIAL SCREW “ as per ISO 10993-18 in biological evaluation report in Annex IX.

Also we mentioned these steps in “ANNEX X Manufacturing Flows for VENUS CERVICAL PLATE SYSTEM “ and “Annex XIII - Manufacturing Flow for Screw”.

CONCLUSION:

The intended use and material oh the subject anterior cervical plate are identical to this of the predicate anterior cervical plates.The predicate STRYKER SPINE NULOCK ANTERIOR CERVICAL PLATING SYSTEM consists of various size plates are implanted and remain static.The subject system introduces various length plates that has antiback out mechanism as predicate device.

Non-clinical testing including Pull-out Test,Driving Torque Test ,Torsion Test ,Self-Tapping Test , Fatigue Test , Static Compression Test , Static Tensile Test and Static Torsion Test were conducted. The results showed that the performance of the proposed devices is substantially equivalent.