Mikron Makina Sanayi ve Ticaret Ltd. Sti.
Mustafa Ekiz
Medical Devices Manager
Ivedik OSB Mahallesi 1372. Sok No:31 Yenimahalle
Ivedik, Ankara 06378
Turkey

April 17, 2024

Re: K240484
Trade/Device Name: MSFX Mikron Cervical Anterior Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 9, 2024
Received: February 20, 2024

Dear Mustafa Ekiz:

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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2024.04.17 07:39:27 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240484

Device Name

MSFX Mikron Cervical Anterior Plate System

Indications for Use *(Describe)*

The MSFX Mikron Cervical Anterior 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: MUSTAFA EKIZ

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ESTABLISHMENT REGISTRATION:3010646402

Secondary Contact Person:

NAME: James Gibson, PHD, CPA,

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Tampa, FL 33612

PHONE- Cell: 813-505-7800

EMAIL: JG@SAGICOUSA.com

DEVICE IDENTIFICATION

TRADE NAME: MSFX MIKRON CERVICAL ANTERIOR PLATE SYSTEM

CLASSIFICATION NAME: APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY

REGULATION NUMBER: 888.3060

REVIEW PANEL: ORTHOPEDIC

PRODUCT CODE: KWQ

REASON FOR SUBMISSION: NEW DEVICE (to be rebranded from the primary predicate device)

INDICATIONS FOR USE:

The MSFX Cervical Anterior 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 MSFX Cervical Anterior Plate System is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation.

The MSFX Mikron cervical anterior plate 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 3.5mm, 4.0mm and 4.5 mm of diameters in lengths of 12 mm – 20 mm. All components made of Ti alloy are subjected to anodizing. The implants (bone screws and cervical plates) are provided as single-use, non-sterile devices manufactured from implantable grade titanium alloy (Ti6Al4V).

The MSFX Cervical Anterior Plate System is supplied non-sterile to be sterilized by end-user by moist-heat, is for single use and is fabricated from titanium alloy (Ti6Al4V-ELI) that conforms to ASTM F136. Various sizes of these components are available to be used by a professional in a healthcare facility/ hospital.

NON-CLINICAL TESTING:

Non-clinical testing including Fatigue Test (ASTM F1717-18) Static Compression Test (ASTM F1717-18), and Static Torsion Test (ASTM F1717-18) were conducted on the predicate device (K211718). As the purpose of this submission is to rebrand the Venus Cervical Plate System (K211718), no new mechanical testing is needed on the subject device.

PRIMARY PREDICATE:

TRADE/ DEVICE NAME: VENUS CERVICAL PLATE SYSTEM

REGULATION NUMBER: 21 CFR 888.3060

REGULATION NAME: APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY

REGULATORY CLASS: Class II

PRODUCT CODE: KWQ

510(K) NUMBER: K211718

ADDITIONAL PREDICATE:

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 :

The MSFX MIKRON CERVICAL ANTERIOR PLATE SYSTEM has similar technological characteristics as the predicate devices, including the materials, design, function, range of sizes, manufacturing process, surgical techniques, and intended use. The minor differences do not present new issues of safety and effectiveness.

CONCLUSION:

Based on the data presented in the submission, the subject device is determined to be substantially equivalent to the predicate.