



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

September 30, 2024

Re: K241657

Trade/Device Name: Msfx Mikron Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: June 3, 2024
Received: June 10, 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.

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,

Eileen

Cadel -

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Digitally signed
by Eileen Cadel

-S

Date:

2024.09.30

14:42:00 -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

Indications for Use

510(k) Number (if known)

K241657

Device Name

MSFX MIKRON SPINAL FIXATION SYSTEM

Indications for Use (Describe)

MSFX MIKRON SPINAL FIXATION SYSTEM is intended for use in the noncervical spine. When used as a posterior, noncervical pedicle and non- pedicle fixation system, the MSFX MIKRON SPINAL FIXATION SYSTEM is intended to provide additional support during fusion using autograft 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) #: K241657

510(k) Summary

Prepared on: 2024-08-24

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Mikron Makina Sanayi ve Ticaret Ltd. Sti.
Applicant Address	Ivedik OSB Mah. 1372. Sok. No:31 Yenimahalle/Ankara/TURKEY Yenimahalle Ankara 06378 Turkey
Applicant Contact Telephone	+903128020066
Applicant Contact	Mr. MUSTAFA EKIZ
Applicant Contact Email	mustafaekiz@mikronmakina.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	MSFX MIKRON SPINAL FIXATION SYSTEM
Common Name	Thoracolumbosacral pedicle screw system
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3070
Product Code(s)	NKB, KWP

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K171497	Mikron Spinal Fixation system	NKB
K212220	Artfx Spinal Fixation System	NKB
K091445	CD HORIZON SPINAL SYSTEM	NKB
K071373	XIA 3 Spinal System	NKB

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

Msfx Mikron Spinal Fixation System is a top-loading, multiple component, posterior spinal fixation system consisting of polyaxial pedicle screws, monoaxial pedicle screws, cannulated and spondylolisthesis screws, rods (Straight and curved) , connectors , hooks and setscrews. It allows surgeons and functions to build a spinal implant construction to stabilize and promote spinal fusion. The System components are supplied non-sterile, for single use and fabricated from titanium alloy (Ti6Al4V-ELI) that conforms to ASTM F136. Various sizes of these components are available.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

MSFX MIKRON SPINAL FIXATION SYSTEM is intended for use in the noncervical spine. When used as a posterior, noncervical pedicle and non- pedicle fixation system, the MSFX MIKRON SPINAL FIXATION SYSTEM is intended to provide additional support during fusion using autograft 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

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Msfx Mikron Spinal Fixation System has the same indications for use with the predicate devices indicated.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Msfx Mikron 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.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Biomechanical tests of the Mikron Spinal Fixation System are performed according to ASTM F1798, ASTM F2193 and ASTM F1717.

The Msfx Mikron Spinal Fixation System is substantially equivalent to the predicate device currently cleared under K171497 as it has the same intended use, same design, principle of operation and technological characteristics. No new questions of safety or effectiveness have been raised as compared to the predicate. Performance testing has demonstrated that the Msfx Mikron Spinal Fixation System is substantially equivalent to the predicate device.