August 13, 2026

Mikron Makina San. ve Tic. Ltd. Sti.
Mustafa Ekiz
Medical Devices Manager
Ivedik Osb Agac Isleri San. Sit.1372. Sok. No:31
Yenimahalle, Ankara 06378
Turkey

Re: K260277
Trade/Device Name: Mikron Trauma Bone Plate& Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTN
Dated: July 14, 2026
Received: July 14, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260277

Please provide the device trade name(s).

MIKRON TRAUMA BONE PLATE& SCREW SYSTEM

Please provide your Indications for Use below.

MIKRON TRAUMA BONE PLATE& SCREW SYSTEM is indicated for fixation of upper extremity (humerus, olecranon, radius, ulna, metacarpals, phalanges), lower extremity (femur, tibia, fibula, tarsals, metatarsals, phalanges), pelvis, and clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions. MIKRON TRAUMA BONE PLATE& SCREW SYSTEM is not intended for use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine, nor for fixation of the sacroiliac joint. The system is intended for single use and for adult patients only.

MIKRON SMALL FRAGMENT PLATES SYSTEM is indicated for the fixation of upper extremity (humerus, olecranon, radius, ulna, metacarpal, phalangeal), fibula, foot (tarsal, metatarsal, phalangeal), pelvis, and clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

MIKRON LARGE FRAGMENT PLATES SYSTEM is indicated for fixation of lower extremity (femur, tibia, fibula) and foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

MIKRON STAND-ALONE BONE SCREWS are indicated for fracture fixation, reconstruction, osteotomy, and arthrodesis of various bones and bone fragments including joint fusions (arthrodeses) in the foot and fixation of intra-articular fractures of the humerus, femur and tibia.

MIKRON MINI PLATES SYSTEM is indicated for fixation of hand (metacarpal, phalangeal) and foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K260277

510(k) Summary

Prepared on: 2026-07-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Mikron Makina San. ve Tic. Ltd. Sti.
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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	MIKRON TRAUMA BONE PLATE& SCREW SYSTEM
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC, HTN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K242939	ARTFX Trauma Bone Plate and Screw System	HRS
K143165	Herbert/Whipple Bone Screw System, Herbert Bone Screw, Herbert Cannulated Bone Screw System, Herbert Mini Bone Screw	HWC
K161616	DePuy Synthes 4.0 mm and 4.5 mm Cortex Screws, DePuy Synthes 2.4 mm Cannulated Screws, DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws, DePuy Synthes 4.5 mm Cannulated Screws, DePuy Synthes 6.5 mm Cannulated Screws, DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws, DePuy Synthes 1.5 mm Headless Compression Screws, DePuy Synthes 2.4 mm Headless Compression Screws, DePuy Synthes 3.0 mm Headless Compression Screws, DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screw	HWC
K160946	4.0 and 6.5 Cancellous Bone Screw and Washer	HWC

Device Description Summary

21 CFR 807.92(a)(4)

Mikron Trauma Bone Plate& Screw System devices are supplied non-sterile and disposable,the components are manufactured from titanium alloy (Ti6Al4V-ELI) conforming to ASTM F136 and must be steam-sterilized prior to use. Mikron Trauma Bone Plate& Screw

System devices can be classified into 4 groups: Small Fragment Plates, Large Fragment Plates, Mini Plates and Screws. These components are available in various sizes.

The subject system includes bone plates and screws that are used in the treatment of fractures, fusions, osteotomies, non-unions, malunions, and reconstructive surgeries of the upper extremity (humerus, olecranon, radius, ulna, metacarpals, phalanges), lower extremity (femur, tibia, fibula, tarsals, metatarsals, phalanges), pelvis, and clavicle. After fracture reduction, these devices provide stability and maintain the alignment of bone fragments throughout the healing process. Compression is used whenever possible to increase the contact area and stability between the fragments and reduce stress on the implant. Compression is achieved by using non-locking screws that are placed in compression slots or holes of the plate, allowing for compression of the bone fragments as the screws are tightened. The locking screws do not provide compression, as they are designed to lock into the plate and stabilize the bone fragments through fixed-angle constructs. The special feature of the subject devices is the free choice of screw placement. The user is able to set any desired screw in any hole (either using a locking or non-locking screw). The free choice of screw angulation provides an advantage in fracture treatment, especially in the case of complex fractures.Generally, the subject plates are designed to the contour of their intended anatomical location and used with cortical, cancellous, non-locking, locking, and cancellous subject screws.

The subject plates of the MIKRON Small Fragment System includes; clavicle shaft locking plate, clavicle distal locking plate, clavicle hook locking plate, humerus proximal locking plate, humerus distal lateral locking plate, humerus distal posterolateral locking plate, humerus distal medial locking plate, olecranon locking plate, olecranon hook locking plate, small 3.5 compression plate, small 3.5 tp2 locking straight plate, tubular locking plate combi hole, tibia distal medial locking plate, tibia distal medial locking plate (3.5), tibia distal lateral locking plate, tibia distal lateral locking plate tp2, calcaneus locking plate, fibula distal locking plate, fibula locking plate, reconstruction shaft locking plate, proximal radius locking plate, distal radius volar locking plate, distal radius volar locking plate small, distal radius volar locking plate tp2, radius distal dorsal t locking plate, radius distal dorsal l locking plate, distal radius staloid plate , ulna proximal hook locking plate, distal ulna locking plate, radius distal/ulna hook locking plate, metacarpal hand/wrist artrodesis plate, pelvic reconstruction curved locking plate, pelvic symphyseal plate 4 holes, pelvic reconstruction straight locking plate, small femur proximal hip locking plate(3.5). The plates of this system range in thickness from 1.4mm to 3.8mm and in width from 6.2mm to 16.0mm.

The subject plates of the MIKRON Large Fragment System includes; the large narrow locking plate, femur proximal locking plate, small femur proximal hip locking plate (5.0), large broad locking plate, femur distal locking plate, large broad locking t plate, large broad t support locking plate, tibia high osteotomy plate, large broad l support locking plate, proximal medial/anteromedial tibia locking plate, tibia proximal lateral locking plate. The plates of this system range in thickness from 3.0mm to 5.5mm and in width from 13.5mm to 17.5mm.

The subject plates of the MIKRON Mini-Plate System includes;1.5mm system, 2.0mm system, 2.5mm system, and 2.7mm system. The 1.5mm system includes; 1.5 mm hand/foot mini non locking mallet finger plate, 1.5 mm hand/foot mini non locking strut plate oblique angled , 1.5 mm hand/foot mini h plate, 1,5 mm hand/foot mini locking t plate head 4 holes, 1.5 mm hand/foot mini locking straight plate, 1.5 mm hand/foot mini non locking straight plate , 1.5 mm hand/foot mini locking t plate head 2 holes, 1.5 mm hand/foot mini locking t plate head 3 holes, 1.5 mm hand/foot mini locking y plate, 1.5 mm hand/foot mini locking condylar plate , 1.5 mm hand/foot mini non locking t plate head 4 holes. The 2.0mm system includes; 2.0 mm hand/foot mini locking straight plate, 2.0 mm hand/foot mini locking t plate head 2 holes, 2.0 mm hand/foot mini locking y plate head 3 holes, 2.0 mm hand/foot mini locking condylar plate, 2.0 mm hand/foot mini locking adaptation straight plate. The 2.5mm system includes; 2.5mm hand/foot locking h plate, hand/foot mini locking straight plate, hand/foot mini locking condylar plate, foot locking x plate, hand/foot mini locking l plate oblique, hand/foot mini locking l plate, hand/foot mini adaptation locked straight plate, and hand/foot mini locking t plate 3 holes. The 2.7mm system includes; 2.7 mm hand/foot mini locking h plate, 2.7 mm hand/foot mini locking straight plate, 2.7 mm hand/foot mini locking t plate, 2.7 mm hand/foot mini locking condylar plate, 2.7 mm hand/foot mini locking x plate, 2.7 mm hand/foot mini locking l plate oblique, 2.7 mm hand/foot mini locking l plate, 2.7 mm hand/foot mini locking adaptation straight plate. Also, metacarpal fusion plate and mini foot metatarsal fusion plates are included in mini-plate system. The plates of the MIKRON Mini- Plate System range in thickness from 0.8mm to 2.5mm.

The subject screws of the MIKRON Bone Screw System includes; locking self-tapping cortical screw, non-locking self-tapping cortical screw, non-locking self-tapping cancellous screw full thread, cannulated screw, locking cannulated screw full thread ,2.5, 3.5, 5.0 mm locking cap screw, locking self-tapping cancellous screw, headless cannulated screw full thread, cannulated cancellous herbert screw, screw stamp. The screws in this system ranges in major diameter from 1.5mm to 7.3mm. The screw stamps have small, medium, large, x-large and xx-large sizes.

MIKRON TRAUMA BONE PLATE & SCREW SYSTEM offers these products in the market under 2 different brands. These are; MSFX and ZETA IMPLANT.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

MIKRON TRAUMA BONE PLATE& SCREW SYSTEM is indicated for fixation of upper extremity (humerus, olecranon, radius, ulna, metacarpals, phalanges), lower extremity (femur, tibia, fibula, tarsals, metatarsals, phalanges), pelvis, and clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions. MIKRON TRAUMA BONE PLATE& SCREW SYSTEM is not intended for use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine, nor for fixation of the sacroiliac joint. The system is intended for single use and for adult patients only.

MIKRON SMALL FRAGMENT PLATES SYSTEM is indicated for the fixation of upper extremity (humerus, olecranon, radius, ulna, metacarpal, phalangeal), fibula, foot (tarsal, metatarsal, phalangeal), pelvis, and clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

MIKRON LARGE FRAGMENT PLATES SYSTEM is indicated for fixation of lower extremity (femur, tibia, fibula) and foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

MIKRON STAND-ALONE BONE SCREWS are indicated for fracture fixation, reconstruction, osteotomy, and arthrodesis of various bones and bone fragments including joint fusions (arthrodeses) in the foot and fixation of intra-articular fractures of the humerus, femur and tibia.

MIKRON MINI PLATES SYSTEM is indicated for fixation of hand (metacarpal, phalangeal) and foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has similar indications for use in comparison to the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same technological characteristics in comparison to the primary predicate device (K242939-ARTFX Trauma Bone Plate and Screw System).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical performance testing for the subject devices has been performed in accordance with ASTM F382-17, ASTM F543-23, and meet the scope and performance criteria outlined in the FDA Guidance for bone screws 'Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway' and for bone plates 'Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway'. The results of the nonclinical performance testing demonstrate that the proposed devices are substantially equivalent.

N/A

Mikron Trauma Bone Plate& Screw System is substantially equivalent to the legally marketed predicate device identified above.