August 28, 2026

Ortler Global Tibbi Gerecler Anonim Sirketi
Victor Weaver
Regulatory Consultant
Ivedikkoy Mah., 1492 Cadde, 17 B, 43, Yenimahalle
Ankara, 06378
Turkey

Re: K261830
Trade/Device Name: FRAXION 3.5 Plate System (Various - See Catalog);FRAXION 4.5 Plate System (Various - See Catalog);FRAXION Mini Plate System (Various - See Catalog);FRAXION Bone Screw System (Various - See Catalog)
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
Dated: June 2, 2026
Received: June 2, 2026

Dear Victor Weaver:

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.	K261830

Please provide the device trade name(s).

FRAXION 3.5 Plate System (Various - See Catalog);
FRAXION 4.5 Plate System (Various - See Catalog);
FRAXION Mini Plate System (Various - See Catalog);
FRAXION Bone Screw System (Various - See Catalog)

Please provide your Indications for Use below.

The FRAXION Trauma Bone Plate and 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. The FRAXION Trauma Bone Plate and 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.

The FRAXION 3.5 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.

The FRAXION 4.5 System is indicated for fixation of lower extremity (femur, tibia, fibula) and foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The FRAXION Mini-Plate 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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K261830

510(k) Summary

Prepared on: 2026-06-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ortler Global Tibbi Gerecler Anonim Sirketi
Applicant Address	IVEDIKKOY MAH., 1492 CADDE, 17 B, 43, YENIMAHALLE ANKARA 06378 Turkey
Applicant Contact Telephone	+905356949313
Applicant Contact	Mr. TAHA CIBIR
Applicant Contact Email	ortlerfda@gmail.com
Correspondent Name	Victor Weaver
Correspondent Address	United States
Correspondent Contact Telephone	+905323973043
Correspondent Contact	Mr. Victor Weaver
Correspondent Contact Email	9342mdd@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FRAXION 3.5 Plate System (Various - See Catalog); FRAXION 4.5 Plate System (Various - See Catalog); FRAXION Mini Plate System (Various - See Catalog); FRAXION Bone Screw System (Various - See Catalog)
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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K242939	ARTFX 3.5 Plate System ; ARTFX 4.5 Plate System; ARTFX Mini Plate System; ARTFX Bone Screw System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The subject FRAXION Trauma Bone Plate and Screw System is submitted as a bundled submission and consists of four sub-systems: the FRAXION 3.5 System, the FRAXION 4.5 System, the FRAXION Mini-Plate System, and the FRAXION Bone Screw System. The subject system consists of bone plates and screw 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 bone plates and bone screws are manufactured from Titanium (Ti6Al4V-ELI) per ASTM F136. The subject devices are supplied non-sterile and must be steam-sterilized prior to use.
The subject plates of the FRAXION 3.5 System consist of the clavicle shaft locking plate combi hole, clavicle distal locking plate combi hole, clavicle hook locking plate combi hole, tubular locking plate, olecranon locking plate, olecranon hook locking plate, humerus distal medial locking plate, humerus distal posterolateral locking plate, humerus distal lateral locking plate, distal ulna locking hook plate, radius distal styloid plate, radius distal dorsal L locking plate, radius distal dorsal T locking plate, proximal radius locking plate, radius distal volar locking plate, radius distal volar locking plate small, radius distal volar locking plate TP2, distal ulna locking plate, small 3.5 compression plate combi hole, small 3.5 TP2 compression plate combi hole, humerus proximal locking plate combi hole, reconstruction shaft locking plate, pelvic reconstruction curving locking plate, pelvic reconstruction straight locking plate, pelvic symphyseal plate. The plates of this system range in thickness from 1.4mm to 4.0mm and in width from 6.0mm to 13.0mm.

The subject plates of the FRAXION 4.5 System consist of the tibia distal medial locking plate, tibia distal lateral locking plate, tibia distal lateral locking plate TP2, large broad T locking plate, large broad L support locking plate, small proximal femur plate, tibia proximal medial plate, large broad T support locking plate, tibia high osteotomy plate, large narrow locking plate, tibia proximal lateral locking plate, femur distal locking plate, femur proximal locking plate, large broad locking plate, fibula locking plate, fibula distal locking plate, calcaneus locking plate. The plates of this system range in thickness from 2.0mm to 5.5mm and in width from 9.5mm to 18.0mm.
The subject plates of the FRAXION Mini-Plate System consist of the 1.5mm system, 2.0mm system, 2.5mm system, and 2.7mm system. The 1.5mm system consists of the 1.5mm hand/foot mini locking strut plate, hand/foot mini H plate, hand/foot mini locking T plate head 3 holes, hand/foot mini locking straight plate, hand/foot mini straight plate non-locking, hand/foot mini locking Y plate, hand/foot mini locking condylar plate, hand/foot mini non-locking T plate, mini non-locking mallet finger plate, and mini locking T plate head 4 holes. The 2.0mm system consists of the 2.0mm hand/foot mini locking straight plate, hand/foot mini locking T plate, hand/foot mini locking condylar plate, hand/foot mini adaptation locking straight plate, and hand/foot mini adaptation locking T plate. The 2.5mm system consists of the 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 consists of the 2.7mm hand/foot locking H plate, hand/foot mini locked straight plate, hand/foot mini locked T plate, hand/foot mini locking condylar plate, foot locking X plate, hand/foot mini locked L plate oblique, hand/foot mini locking L plate. The plates of the FRAXION Mini-Plate System range in thickness from 0.8mm to 2.5mm.
The subject screws of the FRAXION Bone Screw System consist of the locking self tapping cortical screw, non-locking self-tapping cortical screw, non-locking self tapping cancellous screw full thread, non-locking self tapping cancellous screw half thread, non-locking self tapping spongiose screw half thread, cannulated compression screw, locking cannulated full thread screw, locking self tapping cancellous screw, headless cannulated full thread screw, cannulated cancellous Herbert screw, and screw stamps. The screws in this system ranges in major diameter from 1.5mm to 7.3mm. The screw stamps have a thickness of 1.5mm and range in outer diameter from 6.0mm to 12.0mm and inner diameter from 3.0mm to 7.8mm.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The FRAXION Trauma Bone Plate and 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. The FRAXION Trauma Bone Plate and 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.

The FRAXION 3.5 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.

The FRAXION 4.5 System is indicated for fixation of lower extremity (femur, tibia, fibula) and foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The FRAXION Mini-Plate 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 indications for use of the subject device are the same as those of the predicate device. There are no differences in the indications for use between the subject device and the predicate device. Therefore, the subject device has the same intended use as the predicate device, and no new intended use is introduced.

Technological Comparison

21 CFR 807.92(a)(6)

Tabii. Ortopedik plak ve vidalar için energy source ifadesini çıkarmak daha uygun olur.

Updated text:

The subject device has identical technological characteristics to the predicate device. The subject device and predicate device have the same design, materials, chemical composition, principle of operation, method of use, and performance characteristics.

There are no differences in technological characteristics between the subject device and the predicate device. Therefore, the subject device is technologically equivalent to the predicate device and does not raise any new or different questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Artx (predicate/subcontractor) performed non-clinical tests on their medical device. These tests are as follows:The non-clinical tests we conducted on the product line are ASTM F382 and ASTM F543.

They performed Static 4-Point Bending Test for ASTM F382.
They performed Pull-Out Test - Torsion Test - Driving Torque Tests for ASTM F543.

During these tests, they referred to the "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway" and "Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway"published by the FDA.

During these tests, they referred to the "Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway" published by the FDA. The "IV. Testing Performance Criteria" section in the guide referenced the comprehensive test reports and necessary documentation required for the Orthopedic Fracture Fixation Plates.

Also,they referred to the "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway" published by the FDA.The "III. Testing Performance Criteria" section in the guide referenced the comprehensive test reports and necessary documentation required for the Orthopedic Non-Spinal Metallic Bone Screws and Washers.

Another basis for their tests was the comparison with Arfx device's equivalent devices. The submission numbers of the predecessor device, which is the best comparators for the attached tests, was K191793.

While conducting the tests, the ASTM standards we referenced for the test methods are ASTM F543-23 "Standard Specification and Test Methods for Metallic Medical Bone Screws" and ASTM F382-17 "Standard Specification and Test Method for Metallic Bone Plates."

To ensure the validity and safety of Artx test results, they have developed the "Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance-Based Pathway / Axial Tensile Strength / Torsional Strength / Driving Torque / ASTM F543- 23" and 'Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance-Based Pathway / Static Four-Point Bending / ASTM F382-17' and checked that the values in their test results meet or exceed the values in the reference study.

In summary, necessary tests have been conducted and interpreted, and safe results have been provided.

N/A

The subject device is designed to fulfill the requirements of the following recognized standards.

Non-clinical testing was conducted by predicate/subcontractor to compare the performance of the subject device and the predicate devices using identical inputs. Testing results demonstrated that the performance of the subject device is equivalent to the predicate device for each of the technical specifications.A risk analysis was completed, and risk controls were implemented. Performance testing results support claims that the subject device is substantially equivalent to the predicate device with regard to safety and efficacy.

Substantially Fraxion Trauma Plates and Screws have the same intended use and technological characteristics as the predicate devices. Therefore, Fraxion Trauma Plates and Screws are substantially equivalent for their intended use.