December 23, 2024

ARTFX Medical
Ozgen Ozfidan
CEO
50 N Laura St. 25th Floor
Jacksonville, Florida 32202

Re: K242939
Trade/Device Name: ARTFX Trauma Bone Plate and 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: September 24, 2024
Received: September 25, 2024

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 (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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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

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)*
K242939

Device Name
ARTFX Trauma Bone Plate and Screw System

Indications for Use *(Describe)*

The ARTFX 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 ARTFX 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 ARTFX 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 ARTFX 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 ARTFX Mini-Plate System is indicated for fixation of hand (metacarpal, phalangeal) and foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

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.

510(k) Summary
(as required by 21 CFR 807.92)

3.1 Owner/Submitter Information:

Owner: ARTFX MEDICAL LLC

Address: 50 LAURA ST N 25TH FLOOR, JACKSONVILLE, FL, 32202 USA

Phone: +1 917 445 2085

Fax: -

Contact Person: OZGEN OZFIDAN

E-mail: ozgen@artfxmed.com

Establishment Registration #: 3017435639

Date of preparation: December 19, 2024

3.2 Submission Information:

Proprietary or Trade Name: ARTFX Trauma Bone Plate and Screw System

Common or Usual Name: Orthopedic Bone Plates and Screws

Classification Name:

1. 21 CFR 888.3030: Plate, Fixation, Bone,
2. 21 CFR 888.3040: Screw, Fixation, Bone,
3. 21 CFR 888.3030: Washer, bolt nut

Product Code:

1. HRS,
2. HWC,
3. HTN

Device Class: Class II Classification

Panel: Orthopedic

3.3 Device Description

The subject ARTFX Trauma Bone Plate and Screw System is submitted as a bundled submission and consists of four sub-systems: the ARTFX 3.5 System, the ARTFX 4.5 System, the ARTFX Mini-Plate System, and the ARTFX 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 ARTFX 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 ARTFX 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 ARTFX 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 ARTFX Mini-Plate System range in thickness from 0.8mm to 2.5mm.

The subject screws of the ARTFX 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.

3.4 Indications for Use

The ARTFX 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 ARTFX 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 ARTFX 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 ARTFX 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 ARTFX Mini-Plate System is indicated for fixation of hand (metacarpal, phalangeal) and foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

3.5 Substantial Equivalence

The subject ARTFX Trauma Bone Plate and Screw System is submitted as a bundled submission and consists of four sub-systems: the ARTFX 3.5 System, the ARTFX 4.5 System, the ARTFX Mini-Plate System, and the ARTFX Bone Screw System. The following table below lists the predicate device 510(k) numbers used to support substantial equivalence. Each subject sub-system has been aligned with their respective predicate devices.

Subject System(s)	Primary Predicate Device	Additional Predicate Device(s)
ARTFX 3.5 System	K191793 - Nebula Brand Locking Bone Plates and Screws Osteosynthesis Plating System, Nebula Brand of DHS Plating System	K171808 - TDM Plate and Screw System, K161894 - SurgTech Trauma System, K171904 - Tandry Locking Plate System
ARTFX 4.5 System	K191793 - Nebula Brand Locking Bone Plates and Screws Osteosynthesis	K163383 - GREENS BRAND Locking Bone Plates and Screws Osteosynthesis

	Plating System, Nebula Brand of DHS Plating System	Plating System K161894 - SurgTech Trauma System
ARTFX Mini-Plate System	K142419 - Mini and Micro Fragments Reconstruction System-NEOFIX	K171904 - Tandry Locking Plate System,
ARTFX Bone Screw System	K191793 - Nebula Brand Locking Bone Plates and Screws Osteosynthesis Plating System, Nebula Brand of DHS Plating System	-

Reference Device: K212220 – ARTFX Spinal Fixation System

3.6 Comparison of Technological Characteristics

A comparison between the ARTFX Trauma Bone Plate and Screw System and the identified primary and additional predicate devices has been performed, which demonstrated similarities in design, dimensions, and performance criteria. The subject and predicate devices are similar in geometry, intended and indicated uses, materials of manufacture, sterilization methods, and non-clinical performance.

3.7 Non-Clinical Performance Testing*:*

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 non-clinical performance testing demonstrate that the proposed devices are substantially equivalent.

Biocompatibility:

The ARTFX Trauma Bone Plate and Screw System in its final finished form is identical to K212220 – ARTFX Spinal Fixation System in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

3.8 Conclusion:

From the data presented, the ARTFX Trauma Bone Plate and Screw System are substantially equivalent in performance for the indications and predicate devices identified.