May 31, 2024

Tyber Medical, LLC
Nicole Merlini
Regulatory Affairs Specialist
83 S Commerce Way
Suite 310
Bethlehem, Pennsylvania 18017

Re: K241218
Trade/Device Name: Tyber Medical Anatomical Plating 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: April 30, 2024
Received: May 1, 2024

Dear Nicole Merlini:

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,

Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241218

Device Name

Tyber Medical Anatomical Plating System

Indications for Use *(Describe)*

Intended Use:
The intended use of the Tyber Medical Anatomical Plating System is to bridge or otherwise stabilize bone fragments to facilitate healing. It is composed of the Mini-Frag System and Ankle Fracture/ Fusion System with the following indications:

Indications for Use:
Mini-frag System
The Tyber Medical Mini-Frag System is indicated for fixation of fractures, osteotomies, nonunions, malunions, replantations, and fusions of short bones and small fragments of bone including, but not limited to, the hand, wrist, foot, and ankle. The mini-frag system is also intended for reduction and stabilization of non-load bearing long bone fragments. The Tyber Medical Mini-frag System is not for Spinal Use.

Ankle Fracture/Fusion System
Tyber Medical Ankle Fracture/Fusion System is indicated for Use in:
- Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, periarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures;
- In intra- and extra articular fractures, osteotomies, medial malleolar fractures and nonunions of the metaphyseal and diaphyseal region of the distal fibula, and calcaneus;
- In distal tibia/fibula long bones which include the metaphyseal and diaphyseal regions of the tibia and fibula in the ankle.

The Tyber Medical Ankle Fracture/Fusion Plating System is not for Spinal Use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Prepared on: 05/29/2024

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Tyber Medical, LLC
Applicant Address	83 S Commerce Way Suite 310 Bethlehem PA 18017 United States
Applicant Contact Telephone	484-274-4471
Applicant Contact	Mrs. Nicole Merlini
Applicant Contact Email	nmerlini@tybermed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tyber Medical Anatomical Plating System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030, 888.3040
Product Code(s)	HRS, HTN, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K153575	Tyber Medical Trauma Screw System	HWC
K232652	Tyber Medical Anatomical Plating System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

Note: The only subject devices of this Special 510(k) submission are the optional bone screw Washers, and these Washers are only to be used with the non-locking screws in the Mini-frag and Ankle Fracture/Fusion Systems.

Tyber Medical Anatomical Plating System Information
The systems presented in this Special 510(k) submission consist of various bone plates, locking screws, washers, and instruments. The Tyber Medical Anatomical Plating System consists of the following categories:
1.Mini-frag System
2.Ankle Fracture/Fusion System

A description of each system is provided below:
Mini-frag/Small Bone System
The Tyber Medical Mini-frag System is designed to address a variety of indications for short bones and small bone fragments including, but not limited to, the hand, wrist, foot and ankle.

The System will incorporate both Locking Screws and standard non-locking Screws in 2.0, 2.5, 2.7, 3.0, 3.5, and 4.0mm sizes in various lengths. Optional bone screw Washers are available for the non-locking Screws in 2.0mm, 2.7mm, 3.5mm, and 4.0mm sizes. All locking screws can be placed on-axis with the internal plate threads or up to 15 degrees off axis in any direction.

All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws and optional bone screw washers are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with color anodized for sizing.

A full set of Ancillary Instrumentation is available with the system. The instruments are not specific to the system.
The Tyber Medical Mini-frag/Small Bone System is offered both sterile and non-sterile.

Ankle Fracture/Fusion System
The Tyber Medical Ankle Fracture/Fusion System is designed to address a variety of indications in ankle reconstruction mid-shaft and distal tibia/fibula fixation surgery.
The System will incorporate both locking Screws and standard non-locking screws in 2.7, 3.0, 3.5, and 4.0mm sizes in various lengths. Optional bone screw Washers are available for the non-locking Screws in 2.7, 3.5, and 4.0mm sizes. All locking screws can be placed on-axis with the internal plate threads or up to 15 degrees off axis in any direction.

All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws and optional screw washers are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with color anodized for sizing.

A full set of Ancillary Instrumentation) is available with the system. The instruments are not specific to the system.

The Tyber Medical Ankle Fracture/Fusion System is offered both sterile and non-sterile.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Intended Use:
The intended use of the Tyber Medical Anatomical Plating System is to bridge or otherwise stabilize bone fragments to facilitate healing. It is composed of the Mini-Frag System and Ankle Fracture/ Fusion System with the following indications:

Indications for Use:
Mini-frag System
The Tyber Medical Mini-Frag System is indicated for fixation of fractures, osteotomies, nonunions, malunions, replantations, and fusions of short bones and small fragments of bone including, but not limited to, the hand, wrist, foot, and ankle. The mini-frag system is also intended for reduction and stabilization of non-load bearing long bone fragments. The Tyber Medical Mini-frag System is not for Spinal Use.

Ankle Fracture/Fusion System
Tyber Medical Ankle Fracture/Fusion System is indicated for Use in:
•Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, periarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures;
•In intra- and extra articular fractures, osteotomies, medial malleolar fractures and nonunions of the metaphyseal and diaphyseal region of the distal fibula, and calcaneus;
•In distal tibia/fibula long bones which include the metaphyseal and diaphyseal regions of the tibia and fibula in the ankle.
The Tyber Medical Ankle Fracture/Fusion Plating System is not for Spinal Use.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject indications for use are within those of the primary predicate and identical to the relevant sections of the additional predicate indications.

Technological Comparison

21 CFR 807.92(a)(6)

The subject plates and screws are identical to those cleared in the additional predicate system. The washers are similar to those in the primary predicate indications (aid in load distribution at the screw head/bone interface), design, dimensions, material, and operating principle.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

All design contol activities, including verification, validation, and other testing, demonstrates that adding optional screw Washers to the Tyber Medical Anatomical Plating System does not raise any questions of safety or performance and is substantially equivalent to the predicate device(s).