June 23, 2025

Tyber Medical, LLC
Chelsea Smith
Regulatory Affairs Manager
83 South Commerce Way, Suite 310
Bethlehem, Pennsylvania 18017

Re: K242486
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

Dear Chelsea Smith:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 19, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter and 510(k) Summary to correct the official correspondent's address as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Christopher Ferreira, M.S., OHT6: Office of Orthopedic Devices, 301-796-9350, christopher.ferreira@fda.hhs.gov.

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

March 19, 2025

Tyber Medical, LLC
Chelsea Smith
Regulatory Affairs Manager
89 South Commerce Way, Suite 310
Bethlehem, Pennsylvania 18017

Re: K242486
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: February 14, 2025
Received: February 14, 2025

Dear Chelsea Smith:

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,

Thomas Mcnamara -S

For: 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

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)*

K242486

Device Name

Tyber Medical Anatomical Plating System

Indications for Use *(Describe)*

Intended Use:

The Tyber Medical Anatomical Plating System is intended to bridge or otherwise stabilize bone fragments to facilitate healing.

Indications for Use:

Mini-Frag System
The Tyber Medical Mini-Frag System is indicated for fixation of fractures, osteotomies, non-unions, malunions, replantations, and fusion 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
The Tyber Medical Ankle Fracture/Fusion System is indicated for use in:
• Fixation of fractures of the distal tibia including, 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 non-unions of the metaphyseal and diaphyseal region of the distal fibula, and calcaneus;
• In distal tibia/fibula long bones which include the metaphyseal and diaphyseal region of the tibia and fibula in the ankle.
The Tyber Medical Ankle Fracture/Fusion 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.

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510(k) #: **510(k) Summary** Prepared on: 2024-10-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Tyber Medical, LLC
Applicant Address	83 South Commerce Way, Suite 310 Bethlehem PA 18017 United States
Applicant Contact Telephone	267-671-7014
Applicant Contact	Mrs. Chelsea Smith
Applicant Contact Email	csmith@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
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
K232652	Tyber Medical Anatomical Plating System	HRS
K241218	Tyber Medical Anatomical Plating System	HRS
K233423/K222465	Tyber Medical Anatomical Plating System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

This traditional 510(k) is a line extension to the Tyber Medical Anatomical Plating System previously cleared under K232652, K241218, and K233423/K222465. The line extension includes additional plates, screws, washers, trays, and instrumentation to the Tyber Medical Anatomical Plating System.

The Tyber Medical Anatomical Plating System consists of the following categories, subject to this submission, with a brief description of each system below:
1. Tyber Medical Mini-Frag System
2. Tyber Medical Ankle Fracture/Fusion System

Mini-Frag System
The Tyber Medical Mini-Frag System offers a variety of plating options for the fixation of bone fragments. The system incorporates plates of various lengths, thicknesses, and configurations. The system also incorporates standard (non-locking) and locking screws of varying lengths and diameters. The system incorporates optional bone screw washers for non-locking screws at a range of sizes. Additionally, specialized trays are available specific to the Tyber Medical Mini-Frag System. Other ancillary instrumentation is available that is not specific to the Tyber Medical Mini-Frag System.
The plates subject to this submission are composed of Ti-6Al-4V ELI (ASTM F136) with an anodized Type II surface treatment. The screws and bone screw washers are composed of Ti-6Al-4V ELI (ASTM F136) with color anodizing for sizing.

The subject devices are offered 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 incorporates plates of varying lengths, thicknesses, and configurations. The system also incorporates standard (non-locking) and locking screws of varying lengths and diameters. The system incorporates optional bone screw washers for non-locking screws at a range of sizes. Additionally, specialized drill guides and trays are available specific to the Tyber Medical Ankle Fracture/Fusion System. Other ancillary instrumentation is available that is not specific to the Tyber Medical Ankle Fracture/Fusion System.
The plates subject to this submission are composed of Ti-6Al-4V ELI (ASTM F136) with an anodized Type II surface treatment. The screws and bone screw washers are composed of Ti-6Al-4V ELI (ASTM F136) with color anodizing for sizing.
The subject devices are offered non-sterile.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Intended Use:

The Tyber Medical Anatomical Plating System is intended to bridge or otherwise stabilize bone fragments to facilitate healing.

Indications for Use:

Mini-Frag System
The Tyber Medical Mini-Frag System is indicated for fixation of fractures, osteotomies, non-unions, malunions, replantations, and fusion 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
The Tyber Medical Ankle Fracture/Fusion System is indicated for use in:
• Fixation of fractures of the distal tibia including, 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 non-unions of the metaphyseal and diaphyseal region of the distal fibula, and calcaneus;
• In distal tibia/fibula long bones which include the metaphyseal and diaphyseal region of the tibia and fibula in the ankle.
The Tyber Medical Ankle Fracture/Fusion System is not for spinal use.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same for both the subject and predicate device(s).

Technological Comparison

21 CFR 807.92(a)(6)

A comparison of the subject devices and the predicate devices demonstrated that the Tyber Medical Anatomical Plating System are substantially equivalent to the previously cleared Tyber Medical Anatomical Plating System in regards to the intended use/indications for use, material, design, and operational principles.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Nonclinical Testing:
The additional plates and screws were compared using engineering analysis to the predicate devices in K222465. The submitted comprehensive evaluation of the subject plates and screws shows that no new worst case is being introduced in this line extension.

An MR assessment was perform for magnetically induced displacement force in accordance with ASTM F2052, magnetically induced torque in accordance with ASTM F2213, RF-induced heating in accordance with ASTM F2182, and image artifacts in accordance with ASTM F2119 demonstrating that The Tyber Medical Anatomical Plating System is MR Conditional.

Clinical Testing:

Not Applicable.

Conclusions:
The Tyber Medical Anatomical Plating System described in this submission have the same indications for use, intended use, and materials as the predicate devices. The additional plates, screws, and accessory instrumentation have similar technological characteristics as the previously cleared predicate devices. The evidence submitted in this 510(k) demonstrates the subject devices is substantially equivalent to the predicate devices.