March 7, 2023

Tyber Medical, LLC
% Lisa Boyle
Senior Manager, Regulatory Affairs
Tyber Medical, LLC.
83 South Commerce Way
Suite 310
Bethlehem, Pennsylvania 18017

Re: K222465
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
Dated: February 2, 2023
Received: February 3, 2023

Dear Lisa Boyle:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jesse Muir -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222465

Device Name
Tyber Medical Anatomical Plating System

Indications for Use *(Describe)*

Mini-frag System
The Tyber Medical Mini-frag System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of short bones and short bone fragments including, but are not limited to, the hand, wrist, foot and ankle.
The Tyber Medical Mini-frag System is not for Spinal Use.

Foot System
The Tyber Medical Foot System is Indicated for Use in fixation of short bones and short bone fragments in the foot (Phalanges and Metatarsals), and long bones and long bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of short and long bones, revision surgeries and replantations in an adult patient.
The Tyber Medical Foot System is not for Spinal Use.

Long Bone Fracture System
The Tyber Medical Long Bone Fracture System is intended for osteotomies and non-unions, fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, fibula.
The Tyber Medical Long Bone Fracture System is not for Spinal Use.

Ankle Fracture/Fusion System
The Tyber Medical Ankle Fracture/Fusion System is Indicated for Use in:
1). Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, perarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures;
2). 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;
3). 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 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) Summary

Prepared on: 2023-03-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Tyber Medical, LLC.
Applicant Address	83 South Commerce Way Suite 310 Bethelehem PA 18017 United States
Applicant Contact Telephone	610-295-7984
Applicant Contact	Ms. Lisa Boyle
Applicant Contact Email	lboyle@tybermed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tyber Medical Anatomical Plating System
Common Name	Plate, Fixation, Bone; Screw, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories - Primary Smooth or threaded metallic bone fixation fastener
Regulation Number	888.3030 / 888.3040
Product Code	HRS / HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203817	Anatomical Plating System	HRS
K 193222	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 cleared under K203817. The line extension include additional plates and instrumentation to the product line, and updating the device labeling to include MR Conditional information.

Device Description
The Tyber Medical Anatomical Plating System consists of the following categories:
1. Mini-frag System
2. Foot System
3. Long Bone Fracture System
4. Ankle Fracture/Fusion System

A brief and concise description of each system is as follows:

Mini-frag System
The Tyber Medical Mini-frag System offers a variety of plates for fixation of bone fragments. The system incorporates a series of standard and locking compression plates and screws of varying lengths, thicknesses, and configurations including 1). Straight Fracture Plates, 2).

T-shape Fracture Plates, 3). Y-shape Fracture Plates, 4). L-shape Fracture Plates, 5). Cloverleaf plates, 6). Straight Fusion Plates, 7). Oblique Fracture Plates, 8). Oblique Fracture Compression Plates, 9). Double Y-Shape Plates, 10). Zig-Zag Plates, 11). Partial Zig-Zag Plates, 12). Mesh Plates

The System will incorporate both Locking Screws and Non-Locking Screws in 2.0mm, 2.5mm, 2.8mm, 3.0mm and 3.5mm sizes in various lengths. All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws 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 Tyber Medical Mini-frag System is offered both sterile and non-sterile for single-use.

Foot System
The Tyber Medical Foot System consists of a variety of plates with shapes and sizes designed for internal fixation of short bone fragments of the foot. The implants are designed to provide highly anatomic and versatile options for an array of fusions and stabilizations of short bones in the feet. The plates are available in various lengths, with straight, right and left configurations. Plate types consist of 1). TMT-I Fusion Plates, 2). Open Wedge Plates, 3). Navicular Plates, 4). Cuboid Plates, 5). Lateral Talar Neck Plates, 6). Akin Plates, 7). 5th Metatarsal Jones Fracture Plates, 8). 5th Metatarsal Fracture Compression Plates, 9). 5th Metatarsal Avulsion Fracture Plates, 10). Medial Talar Neck Plates, 11). Distal Medial Column Plates, 12). ORIF Calcaneal Plates, 13). ORIF Standard Calcaneal Plates, 14). Rectangular Plates, 15). X-Plates, 16). Cotton Plates, 17). Dwyer Plates, 18). MTP Fusion Plates, 19). MTP Fusion Revision Plates, 20). Stepped Lapidus Plates, 21). Plantar TMT Plates, 22). Medial Column Plates, 23). Evans Osteotomy Plates, 24). TMT-I Medial Fusion Plates, 25). Sinus Tarsi Plates, 26). 1st 2nd Ray Lisfranc Joint Plates, 27). 2nd and 3rd Ray Lisfranc Joint Plates, 28). Perimeter Calcaneus Plates, 29). Navicular Cuneiform Plates, 30). Talonavicular Plates.

The system will incorporate both locking and Non-locking screws. All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws 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 Tyber Medical Foot System is offered both sterile and non-sterile for single-use.

Long Bone Fracture System
The Tyber Medical Long Bone Fracture System consists of a straight low contact locking plate and a 1/3 locking tubular plate. The system will incorporate both Cortical locking and standard Cortical Non-locking screws. All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws 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 Tyber Medical Long Bone Fracture System is offered both sterile and non-sterile for single-use.

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 is composed of various locking plate types which include 1). Posterior Tibia Plate, 2). Fibula Plate, 3). Medial Tibia Plate, 5). Anterolateral Tibia Plate, 6). Medial Malleolus Hook Plate, 7). Medial Malleolus Plate, 8). Fibula Hook Plate, Straight, 9). Fibula Hook Plate, Anatomic, 10). Anterior Tibia Plate, 11). Anterior TT Plate, 12). Anterolateral TT Plate, 13). Lateral TT Plate, 14). Lateral TTC Plate, 15). Posterior TTC Plate, 16). Posterolateral Tibia Plate, 17). Posteromedial Tibia Plate, 18). Trimalleolar Plate, 19). Posterior Fibular Plate.

The System will incorporate both Locking Screws and Non-locking Screws in various lengths. All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws 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 Tyber Medical Ankle Fracture/Fusion System is offered both sterile and non-sterile for single-use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Mini-frag System
The Tyber Medical Mini-frag System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of short bones and short bone fragments including, but are not limited to, the hand, wrist, foot and ankle.

The Tyber Medical Mini-frag System is not for Spinal Use.

Foot System
The Tyber Medical Foot System is Indicated for Use in fixation of short bones and short bone fragments in the foot (Phalanges and Metatarsals), and long bones and long bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of short and large bones, revision surgeries and replantations in an adult patient.

The Tyber Medical Foot System is not for Spinal Use.

Long Bone Fracture System
The Tyber Medical Long Bone Fracture System is intended for osteotomies and non-unions, fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, fibula.

The Tyber Medical Long Bone Fracture System is not for Spinal Use.

Ankle Fracture/Fusion System
The Tyber Medical Ankle Fracture/Fusion System is Indicated for Use in:
1). Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, perarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures;
2). 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;
3). 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 System is not for Spinal Use.

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

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

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has similiar technological characteristics (design, material, chemical composition and principle of operation) as the predicate device identified above. This submission is a line extension to K203817 which incorporates additional plates, screws, and instrumentation to the product line, and updates the device labeling to include MR Conditional information.

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

The additional plates and screws were compared using engineering analysis to the predicate devices in submission K203817. The submitted comprehensive evaluation of all plates and screws shows that no new worse case is being introduced in this line extension.

MRI testing as listed below was performed. Results showed that the devices are MR Conditional.
1. Magnetically induced displacement force (ASTM F2052).
2. Magnetically induced torque (ASTM F2213).
3. MR image artifact (ASTM F2119).
4. Radio frequency induced heating (ASTM F2182).

No clinical testing was performed.

The Tyber Medical Anatomical Plating System is substantially equivalent to the predicate devices in material, basic design features, intended use, operation and performance. Any differences between the subject and predicate device are considered minor and do not raise different questions concerning safety, performance or effectiveness. From the evidence submitted in this 510(k), the subject devices are considered substantially equivalent to the predicate device.