January 20, 2020

Tyber Medical LLC
Jessica Stigliano
Regulatory Affairs Specialist
83 South Commerce Way, Suite 310
Bethlehem, Pennsylvania 18017

Re: K193222
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: November 22, 2019
Received: November 22, 2019

Dear Jessica Stigliano:

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,

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)*
K193222

Device Name
Tyber Medical Anatomical Plating System

Indications for Use *(Describe)*
The intended use of the Tyber Medical Anatomical Plating System is to draw two or more aligned bone fragments together to facilitate healing in an adult patient and is composed of the following bone plate categories:

I. Forefoot System:
The Tyber Medical Forefoot Plating System is Indicated for Use in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of small bones, revision surgeries and replantations in an adult patient.
The Tyber Medical Forefoot System is not for Spinal Use.

II. Mid & Hindfoot System:
The Tyber Medical Mid & Hindfoot Plating System is Indicated for Use in fixation of medium/large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of medium/large bones, revision surgeries and replantations in an adult patient.
The Tyber Medical Mid & Hindfoot System is not for Spinal Use.

III. Ankle Fracture System:
The Tyber Medical Ankle Fracture 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;
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 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.

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Traditional 510(k) Summary

as required by section 807.92(c).

Tyber Medical
Anatomical Plating System

K193222

Submitted	11/20/2019
Submitter:	Tyber Medical LLC 83 South Commerce Way, Suite 310 Bethlehem, PA 18017
Contact Person	Primary Contact: Jessica Stigliano Regulatory Affairs Specialist Phone: 866-761-0933 (ext. 424) Fax: (866) 889-9914 Email: jstigliano@tybermed.com Secondary Contact: Mark Schenk V.P. Regulatory Phone: 610-849-0645 Email: mschenk@tybermed.com
Trade Name	Tyber Medical Anatomical Plating System
Common Name	Plate, Fixation, Bone; Screw, Fixation, Bone
Device Class	Class II
Classification Name and Number	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030) Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Classification Panel:	Orthopedic
Product Code	HRS/HWC
Predicate Devices	BioPro Foot Plating Systems – K162674
Device Description	The Tyber Medical Anatomical Plating System consists of the following categories: 1. Forefoot System 2. Mid & Hindfoot System 3. Ankle Fracture System

	A brief and concise description of each system is as follows: **Forefoot System** The Tyber Medical Forefoot System is designed to address a variety of indications in forefoot reconstruction fixation/osteotomy surgery. The system is composed of many locking plate types which include: 1). Straight Fracture Plates, 2). T-Shaped Fracture Plates, 3). Y-Shape Fracture Plates, 4). L-Shaped Fracture Plates, 5). Cloverleaf Fracture Plates, 6). TMT 1 Medial Fusion Plates, 7). Open Wedge Fusion Plates, 8). MTP Fusion Plates, 9). MTP Fusion Revision Plates, and 10). Dorsal TMT 1 Step Fusion Plates, - in various plate lengths, Right & Left versions. The System will incorporate both Cortical Locking Screws and standard Cortical Screws in 2.0mm, 2.5mm, 2.8mm, 3.0mm and 3.5mm sizes in various lengths. All plates are composed of Medical Grade CP Titanium material (to ASTM F67) with an Anodized Type II surface treatment. All screws are composed of Medical Grade 6-4 Alloyed Titanium material (to ASTM F136) color anodized for sizing. A full set of Ancillary Instrumentation is available with the system. The Tyber Medical Forefoot System is offered both sterile and non-sterile for single-use. **Mid and Hindfoot System** The Tyber Medical Mid & Hindfoot System is designed to address a variety of indications in midfoot & hindfoot reconstruction fixation/osteotomy surgery. The system is composed of many locking plate types which include: 1). Straight Fracture/Fusion Plates, 2). T-Shaped Fracture/Fusion Plates, 3). L-Shaped Fracture/Fusion Plates, 4). Cloverleaf Fracture/Fusion Plates, 5). X-Shaped Fracture/Fusion Plates, 6). Retangular Fracture/Fusion Plates, 7). Cotton Osteotomy Plates, 8). Dwyer Step Plates, 9). Evans Osteotomy Plates, 10.) Plantar TMT Plates, 11). Distal Medial & 3 - 4 Column Plates and 11). ORIF & Standard Calcaneal Plates – in various plate lengths, Right & Left versions. The System will incorporate both Cortical Locking Screws and standard Cortical Screws in 3.0mm, 3.5mm and 4.0mm sizes in various lengths. All plates are composed of Medical Grade CP Titanium material (to ASTM F67) with an Anodized Type II surface treatment. All screws are composed of Medical Grade 6-4 Alloyed Titanium material (to ASTM F136) color anodized for sizing. A full set of Ancillary Instrumentation is available with the system. The

	Tyber Medical Mid and Hindfoot System is offered both sterile and non- sterile for single-use. **Ankle Fracture System** The Tyber Medical Ankle Fracture 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 many locking plate types which include: 1). Distal Fibula Plates, 2). Medial Distal Tibia Plates, 3). AnteroLateral Distal Tibia Plates, 4). Posterior Distal Tibia T-Plates, 5). Straight Low Contact Plates, and 6). Straight 1/3 Tubular Plates – in various plate shapes, lengths, Right & Left versions. The System will incorporate both Cortical Locking Screws and standard Cortical Screws in 2.8mm, 3.0mm, 3.5mm and 4.0mm sizes in various lengths. All plates are composed of either Medical Grade CP Titanium (to ASTM F67) or 6-4 Alloyed Titanium (to ASTM F136) materials with an Anodized Type II surface treatment. All screws are composed of Medical Grade 6-4 Alloyed Titanium material (to ASTM F136) color anodized for sizing. A full set of Ancillary Instrumentation is available with the system. The Tyber Medical Ankle Fracture System is offered both sterile and non-sterile for single-use.

Intended Use	The intended use of the Tyber Medical Anatomical Plating System is to draw two or more aligned bone fragments together to facilitate healing in an adult patient
Indications for Use	I. Forefoot System: The Tyber Medical Forefoot Plating System is Indicated for Use in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of small bones, revision surgeries and replantations in an adult patient. The Tyber Medical Forefoot Plating System is not for Spinal Use. II. Mid & Hindfoot System: The Tyber Medical Mid & Hindfoot Plating System is Indicated for Use in fixation of medium/large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of

	medium/large bones, revision surgeries and replantations in an adult patient. The Tyber Medical Mid & Hindfoot Plating System is not for Spinal Use. III. Ankle Fracture System: The Tyber Medical Ankle Fracture 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; 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 System is not for Spinal Use.

Statement of Technological Comparison and Fundamental Scientific Technology	The Tyber Medical Anatomical Plating System is the same in design, material, technological characteristics and indications when compared to the predicate, BioPro Foot Plating Systems (K162674).

Nonclinical Testing Summary	There have been no changes to the design, material, technological characteristics or indications of the plating systems since receiving clearance in K162674. Therefore, nonclinical testing is not provided in this submission.
Clinical Test Summary	n/a

Conclusion	The Tyber Medical Anatomical Plating System is the same in design, material, technological characteristics, and indications when compared to the BioPro Foot Plating Systems (K162674).