December 20, 2023

Tyber Medical, LLC.
Lisa Boyle
Director, Regulatory Affairs
83 S. Commerce Way
Suite 310
Bethlehem, Pennsylvania 18017

Re: K233017
Trade/Device Name: TM 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: September 8, 2023
Received: September 22, 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 (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,

Shumaya Ali -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233017

Device Name
TM Plating System

Indications for Use *(Describe)*
The TM Plating System is intended to bridge or otherwise stabilize bone fragments to facilitate healing. It is composed of the following indication categories:

I. TM Plating System – Complete Articular
The TM Plating system is indicated for the treatment of nonunions, malunions, osteotomies, and fractures of the femur and tibia. This includes simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures, periprosthetic, and fractures with associated shaft fractures.

II. TM Plating System – Partial Articular
The partial articular (also called buttress or anti-glide) proximal tibia plates are indicated for stabilization and reduction of proximal tibia fragments and treatment of partial articular fractures of the proximal tibia (AO/OTA Fracture Classifications Type B). The partial articular straight plates are indicated for stabilization and reduction of long bone fragments and partial articular fractures of the distal and proximal tibia (AO/OTA Fracture Classifications Type B), and for fracture fixation of the fibula.

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: 2023-12-18

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	610-295-7984
Applicant Contact	Mrs. Lisa Boyle
Applicant Contact Email	lboyle@tybermed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TM Plating System
Common Name	Plate, Fixation, Bone; Screw, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Regulation Number	888.3030 (primary), 888.3040 (secondary)
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
K222381	Stryker Ax SOS 3 Ti	HRS
K210837	Smith & Nephew Plates and Screws	HRS
K222465	Tyber Medical Anatomical Plating System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The system presented in this 510(k) submission consists of various bone plates, locking screws, and instruments. The TM Plating System consists of the following indication categories:
1. Complete Articular (All OA/OTA fracture classification types)
2. Partial Articular (OA/OTA fracture classification type B)

A description of each category is provided below:

Tm Plating System – Complete Articular
The TM System is designed to address a variety of indications for long bones of the tibia and femur. The system is composed of a Straight Plate and a Lateral Proximal Tibia Plate.

TM Plating System – Partial Articular
The Partial Articular plates of TM Plating System are designed to address specific indications for long bones of the tibia and fibula. These buttress (anti-glide) plates are designed for stabilization and reduction of bone fragments, and are intended to treat OA/OTA fracture classification type B fractures only.

The system will incorporate variable angle locking and non-locking screws in various lengths and diameters.

All plates and screws are composed of Ti-6Al-4V ELI (ASTM F136).

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

The TM Plating System plates are offered non-sterile only. The screws offered in this system have already been cleared in K222465 and are offered in both sterile and non-sterile.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The TM Plating System is intended to bridge or otherwise stabilize bone fragments to facilitate healing. It is composed of the following bone plate categories:

I. TM Plating System – Complete Articular
The TM Plating system is indicated for the treatment of nonunions, malunions, osteotomies, and fractures of the femur and tibia. This includes simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, diaphyseal, metaphyseal, epiphyseal, extra-and intra-articular fractures, periprosthetic, and fractures with associated shaft fractures.

II. TM Plating System – Partial Articular
The partial articular (also called buttress or anti-glide) proximal tibia plates are indicated for stabilization and reduction of proximal tibia fragments and treatment of partial articular fractures of the proximal tibia (AO/OTA Fracture Classifications Type B). The partial articular straight plates are indicated for stabilization and reduction of long bone fragments and partial articular fractures of the distal and proximal tibia (AO/OTA Fracture Classifications Type B), and fracture fixation of the fibula.

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

The indications are similar in both the subject and predicate device(s).

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has similar technological characteristics (design, material, chemical composition and principle of operation) as the predicate device(s) identified above.

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

The mechanical testing for the subject devices were performed in conformance with the FDA currently-recognized version of ASTM F382 for metallic bone plates.

No clinical testing was performed.

The TM 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.