July 30, 2025

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

Re: K251361
Trade/Device Name: Tyber Medical Distal Radius 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: April 30, 2025
Received: May 1, 2025

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.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251361

Please provide the device trade name(s).

Tyber Medical Distal Radius Plating System

Please provide your Indications for Use below.

The Tyber Medical Distal Radius Plating System includes Distal Radius, Forearm, and Fragment-Specific Plates, which are indicated for fixation of fractures, fusions, non-unions and malunions, or osteotomies of the radius, ulna, and hand.

The Tyber Medical Distal Radius Plating System is not for spinal use.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251361

510(k) Summary

Prepared on: 2025-07-29

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	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 Distal Radius 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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232693	Tyber Medical Distal Radius Plating System	HRS
K233665	DePuy Synthes VOLT Mini Fragment Plating System, DePuy Synthes VOLT Small Fragment Plating System	HRS
K193554	APTUS® Forearm Shaft Plates and APTUS® Wrist 2.5 System	HRS
K182492	GEMINUS Distal Radius System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

This traditional 510K is a line extension to the Tyber Medical Distal Radius Plating System, previously cleared under K232693. The extension includes additional plates, screws, pegs, cases and trays, and instrumentation.

The Tyber Medical Distal Radius System provides fixation of fractures, fusions, non-unions and malunions, or osteotomies of the radius, ulna, and hand.

The implants – delivered sterile or non-sterile – are:
• Various bone plates of different shapes and hole configurations.
• Variable angle locking and non-locking screws in various lengths and diameters.

The implants are manufactured from Stainless Steel per ASTM F138, from Titanium alloy per ASTM F136, or Commercially Pure Titanium grade 4 per ASTM F67.

The instruments – delivered sterile and non-sterile – are intended to support the implantation of the Tyber Medical Distal Radius Plating

System implants. Specialized cases/trays are available specific to the Tyber Medical Distal Radius Plating System. Other ancillary instrumentation is available but not specific to the Tyber Medical Distal Radius Plating System.

The Tyber Medical Distal Radius Plating System is offered both sterile and non-sterile.

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

The Tyber Medical Distal Radius Plating System includes Distal Radius, Forearm, and Fragment-Specific Plates, which are indicated for fixation of fractures, fusions, non-unions and malunions, or osteotomies of the radius, ulna, and hand.

The Tyber Medical Distal Radius Plating System is not for spinal use.

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

Indications are the same.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same 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 F543 for metallic bone screws (e.g., torsional strength, driving torque, and axial pullout) . Additionally, an engineering analysis showed that the subject plate designs have improved resistance to bending due to the higher moment of inertia.

No clinical testing was performed.

The Tyber Medical Distal Radius Plating System described in this submission have the same indications for use and technological characteristics as the predicate devices. The additional plates, screws, pegs, and instrumentation have similar materials as the previously cleared predicate devices. The mechanical testing demonstrates the performance of the subject devices is equivalent to the predicate devices.