July 6, 2023

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

Re: K231339
Trade/Device Name: Tyber Medical Pin and Wire System (various)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: May 8, 2023
Received: May 8, 2023

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 (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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K231339

Device Name
Tyber Medical Pin and Wire System

Indications for Use *(Describe)*

The Tyber Medical Pin and Wire System is indicated for use in fixation of small bone fractures (e.g., small bone fragment(s) of hand or foot), bone reconstructions, and as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

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: 2023-05-08

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 Pin and Wire System (various)
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Pin, Fixation, Smooth
Regulation Number	888.3040
Product Code	HTY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K083490	BioPro K-Wire	HTY
K100736	SMT Schilling Metalltechnik GmbH	HTY

Device Description Summary

21 CFR 807.92(a)(4)

The Tyber Medical Pin and Wire System is designed for hand, foot, and small bone fragment repairs or fusions. Uses include fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants. It is manufactured from stainless steel, and Titanium Alloy. They are available in a variety of lengths, diameters, and tips to accommodate different anatomic sizes of patients. The devices are provided non-sterile and sterile, single use. Non-sterile devices are intended to be sterilized at the point of use.
The pins and wires are made from stainless steel (316L per ASTM F-138) and titanium alloy (Ti-Al-4V ELI per ASTM F136).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Tyber Medical Pin and Wire System is indicated for use in fixation of small bone fractures (e.g., small bone fragment(s) of hand or foot), bone reconstructions, and as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeleton system.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are similar in both the subject and predicate devices.

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 identified above.

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

The Tyber Medical Pins and Wire have the same intended use and indications for use as the predicate device. The subject devices use the same operating principle, incorporate the same basic design, and are manufactured and sterilized using the same materials and processes as the predicate devices. As such, the Tyber Medical Pin and Wires has been determined to be safe and effective as the predicate device and no new or different questions were raised regarding the safety and effectiveness when compared to the predicate device. Therefore, the devices have been found to be substantially equivalent.

No clinical testing was preformed.

The Tyber Medical Pin and Wire System is substantially equivalent to the predicate devices.