January 8, 2020

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

Re: K192974
Trade/Device Name: Tyber Medical Trauma Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 8, 2019
Received: November 12, 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, MPH
Assistant Director
DHT6A: Division 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)*
K192974

Device Name
Tyber Medical Trauma Screw

Indications for Use *(Describe)*
The Tyber Medical Trauma Screw is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

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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Traditional 510(k) Summary

as required by section 807.92(c).

Tyber Medical
Trauma Screw

K192974

Submitted	10/23/2019
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 Trauma Screw
Common Name	Bone Compression Screw
Device Class	Class II
Classification Name and Number	Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Classification Panel:	Orthopedic
Product Code	HWC
Predicate Devices	Tyber Medical Trauma Screw – K133842
Device Description	General trauma screw for compression and fixation of bone. The purpose of this submission is to add MR Conditional information to the device labeling for K133842. The intended use and technological characteristics of the device remain unchanged.

Intended Use	A trauma screw designed to apply compression and fixation between two adjacent segments of cortical and/or cancellous bone.
Indications for Use	The Tyber Medical Trauma Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

Statement of Technological Comparison and Fundamental Scientific Technology	The purpose of this submission is to add MR Conditional information to the device labeling. Tyber Medical Trauma Screw and its predicate devices have the same indications for use, similar design, same materials, and technology principles of operation.

Nonclinical Testing Summary	**MR Safety Testing** Non-clinical testing is provided to support the conditional safety of Tyber Medical Trauma Screw in the MR environment. The following MRI safety evaluations that were performed (in accordance with ASTM 2503-13) are listed below along with the associated ASTM standard test methods. • Magnetically induced displacement force: ASTM F2052-15 • Magnetically induced torque: ASTM F2213-17 • MR image artifact: ASTM F2119-07 • RF-induced heating: ASTM F2182-11a The non-clinical performance data demonstrate that when exposed to the MR environment under specific MR conditions of use, the Tyber Medical Trauma Screw raises no new questions of safety or effectiveness. **Mechanical Testing** The following mechanical testing has been conducted for the subject device and predicate device: • Driving Torque per ASTM F543-17 Annex A2 The driving torque performance of the subject device has been determined to be greater than or equivalent to the predicate device, and do does not raise any new issues of safety and effectiveness.
Clinical Test Summary	n/a

Conclusion	The purpose of this submission is to add MR Conditional information to the device labeling. Tyber Medical Trauma Screw and its predicate device have the same indications for use, similar design, and technology principles of operation.