DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2016

Tyber Medical LLC
Mark Schenk
Director of Quality Assurance and Regulatory Affairs
89 Headquarters Plaza North, #1464
Morristown, New Jersey 07960

Re: K153575
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: December 22, 2015
Received: December 29, 2015

Dear Mr. Schenk:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153575

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Special 510(k) Summary

as required by section 807.92(c).

Tyber Medical
Trauma Screw

K 153575

Submitted	2/25/16
Submitter:	Tyber Medical LLC 89 Headquarters Plaza North, #1464 Morristown, New Jersey 07960
Contact Person	Mark F Schenk Director of QA/RA Phone: (610) 507-8255 Fax: (866) 889-9914 Email: mschenk@tybermed.com
Trade Name	Tyber Medical Trauma Screw
Common Name	Bone Compression Screw
Device Class	Class II
Regulation 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
Reference Device for surface treatment	Tyber Medical MST Trauma Screw – K153180
Device Description	General trauma screw for compression and fixation of bone. This submission adds a headed screw and snap off option as well as an optional washer to the previously cleared headless trauma screw with and without previously cleared modified surface treatment. The screws will be provided sterile and non-sterile in both solid and cannulated form, made of from titanium (with and without Modified Surface treatment) and Stainless Steel.

Intended Use	A trauma screw designed to apply compression and fixation between two adjacent segments of cortical and/or calcaneus bone.
Indications for Use	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.

Statement of Technological Comparison and Fundamental Scientific Technology	Tyber Medical Trauma Screw and its predicate device have the same indications for use, similar design, same materials, technology principles of operation and test results.

Nonclinical Testing Summary	The following tests were performed to demonstrate that the Tyber Medical Trauma Screw is substantially equivalent to the predicate device (K133842). • Static Torsion Test per ASTM F543 The results of these studies showed that the Tyber Medical Trauma Screw met the acceptance criteria. Additional engineering analysis of the new device and the predicate was also performed to demonstrate substantial equivalence.
Clinical Test Summary	n/a

Conclusion	Tyber Medical Trauma Screw and its predicate device have the same indications for use, similar design, and test results. Both devices are manufactured using materials with a long history of use in orthopedic implants. Therefore, the subject device was shown to be substantially equivalent to the predicate device.