DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 20, 2017

Tyber Medical, LLC
Mark Schenk
Vice President Of Regulatory And Quality
83 S Commerce Way, Suite 310
Bethlehem, Pennsylvania 18017

Re: K170571
Trade/Device Name: Tyber Medical BioTy™ Nanotopography Trauma Screw, TyFix Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 15, 2017
Received: May 16, 2017

Dear Mark 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 Part 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" (21 CFR 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,

Mark N. Melkerson -S

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)*
K170571

Device Name
Tyber Medical BioTy™ Nanotopography Trauma Screw, TyFix Screw

Indications for Use *(Describe)*

The Tyber Medical BioTy™ Nanotopography Trauma Screw, TyFix Screw is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion appropriate for the size of the device. The screw is 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

BioTy™ Nanotopography Trauma Screw, TyFix Screw

K170571

Submitted	6/5/17
Submitter:	Tyber Medical, LLC 83 South Commerce Way, Ste 310 Bethlehem, PA 18017
Contact Person	Mark F Schenk VP of QA/RA Phone: (610) 849-0645 Fax: (866) 889-9914 Email: mschenk@tybermed.com
Trade Name	Tyber Medical BioTy™ Nanotopography Trauma Screw, TyFix 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 BioTy™ Nanotopography Trauma Screw – K161597 Tyber Medical Trauma Screw – K133842
Reference Predicate	Wright Medical PRO-TOE® - K120645
Device Description	General trauma screw for compression and fixation of bone. The BioTy™ Nanotopography provides a microscopic roughened surface with nano-scaled features. The screws will be provided sterile in both solid and cannulated form, made of from titanium and stainless steel.

Intended Use	A Tyber Medical BioTy™ Nanotopography Trauma Screw is designed to apply fixation between two adjacent segments of cortical and/or cancellous bone.
Indications for Use	The Tyber Medical BioTy™ Nanotopography Trauma Screw, TyFix Screw is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion appropriate for the size of the device. The screw is intended for single use only.

Statement of Technological Comparison and Fundamental Scientific Technology	Tyber Medical BioTy™ Nanotopography Trauma Screw, TyFix Screw and its predicate device have the same indications for use and the same design on the threaded end of the device, and the same materials, technology and principles of operation and test results. This submission adds a barbed end that is a similar design, materials, technology and principles of operation to the reference predicate.

Nonclinical Testing Summary	The following tests were performed to demonstrate that the Tyber Medical BioTy™ Nanotopography Trauma Screw is substantially equivalent to other predicate device. • Pull out Test per ASTM F543 • Static Torsion Test per ASTM F543 • Pyrogenicity testing was performed per ST72:2011 The results of these studies showed that the Tyber Medical BioTy™ Nanotopography Trauma Screw met the acceptance criteria.
Clinical Test Summary	n/a

Conclusion	Tyber Medical BioTy™ Nanotopography Trauma Screw, TyFix Screw and its predicate devices 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.