DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 16, 2016

Tyber Medical LLC
Mark Schenk
Vice President Of Regulatory And Quality
89 Headquarters Plaza North, #1464
Morristown, New Jersey 07960

Re: K161597
Trade/Device Name: Tyber Medical BioTy® Nanotopography 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: October 26, 2016
Received: October 31, 2016

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 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 yours,

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)*
K161597

Device Name
Tyber Medical BioTy® Nanotopography Trauma Screw

Indications for Use *(Describe)*
The Tyber Medical BioTy® Nanotopography 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. 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.

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Traditional 510(k) Summary

as required by section 807.92(c).

Tyber Medical

BioTy® Nanotopography Trauma Screw

K161597

Updated	11/14/16
Submitter:	Tyber Medical LLC 89 Headquarters Plaza North, #1464 Morristown, New Jersey 07960
Contact Person	Mark F Schenk Vice President of Regulatory and Quality Phone: (610) 849-0645 Fax: (866) 889-9914 Email: mschenk@tybermed.com
Trade Name	Tyber Medical BioTy® Nanotopography 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 MST Trauma Screw – K153180 Tyber Medical Trauma Screw – K153575
Device Description	This traditional 510(k) is intended to modify the description of the surface treatment of Trauma Screw. General trauma screw for compression and fixation of bone that is provided with and without BioTy® Nanotopography Surface Treatment. The screws are provided headless, headed, and snap-off. The screws will be provided sterile and non-sterile in both solid and cannulated form, made of from titanium (with and without BioTy® Nanotopography Surface Treatment). The subject device is only provided sterile. There are no dimensional changes to the device with this submission, the purpose is to modify the description of the surface treatment. The BioTy® Nanotopography surface treatment provides a roughened surface with nano-scale features. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4VELI).

Intended Use	A trauma screw with BioTy® Nanotopography Surface Treatment is designed to apply compression and fixation between two adjacent segments of cortical and/or cancellous bone.
Indications for Use	The Tyber Medical BioTy® Nanotopography 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. The screw is intended for single use only.

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

Nonclinical Testing Summary	No new mechanical testing in regards to the strength of the implant was performed for this submission because the devices are identical to previously cleared devices. The purpose of this submission is to add detail to the description of the modified surface treatment. Additional invitro testing and engineering analysis of the surface treatment was performed. Pyrogenicity testing was performed per ST72:2011.
Clinical Test Summary	n/a

Conclusion	The Tyber Medical BioTy® Nanotopography Trauma Screw and its predicate device have the same indications for use, and the same design, and test results. Both devices are manufactured using materials with a long history of use in orthopedic implants.