



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

Tyber Medical LLC
Mark F. Schenk
Vice President of Regulatory and Quality
83 S Commerce Way, Suite 310
Bethlehem, Pennsylvania 18017

May 16, 2017

Re: K171327

Trade/Device Name: Tyber Medical Wedge System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: PLF, HRS, HWC
Dated: May 5, 2017
Received: May 5, 2017

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171327

Device Name

Tyber Medical Wedge System

Indications for Use (Describe)

PEEK System Indications

The Tyber Medical Wedge System is intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot such as:

Cotton and Evans Wedges

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Opening wedge of Medial Cuneiform of Cotton osteotomies
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)

Midfoot Wedges

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

The device is intended for use with ancillary fixation

The Tyber Medical Wedge System is not intended for use in the spine

TyPEEK System Indications

The Tyber Medical Wedge System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot such as:

Cotton and Evans Wedges

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
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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.

510(k) Summary of Safety and Effectiveness:

TYBER MEDICAL Wedge System

Submitter by:	Tyber Medical LLC 83 South Commerce Way Suite 310 Bethlehem, PA 18017
Contact Person	Mark F. Schenk Vice President of Regulatory and Quality Phone: (610) 849-0645 Fax: (866) 889-9914 Email: mschenk@tybermed.com
Date Prepared	May 12, 2017
Common Names	Bone Wedge Osteotomy Bone Wedge
Trade Name	Tyber Medical Wedge System
Classification Name and Number	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030) Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Product Code	PLF, HRS and HWC
Predicate Device	Tyber Medical Wedge System (K150394)
Device Description	This submission is to add additional footprints to the system. The Tyber Medical Wedge System, manufactured from PEEK-Optima[®], consist of implants available in various foot prints, heights and indication configurations with an open architecture to accept packing of bone graft materials. The exterior of the device has "teeth" or other generally sharp engagement members on the superior and inferior surfaces. The device comes in a PEEK or PEEK with a plasma-sprayed commercially pure titanium coating on the superior and inferior surfaces.

**Intended Use/
Indications for use**

PEEK System Indications

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**Performance Data
(Non-Clinical)**

- The worst-case device has not changed from the prior submission and so no new testing has been completed.
- Pyrogenicity testing was performed per ST72:2011.

**Performance Data
(Clinical)**

Clinical data and conclusions were not needed for this device.

**Statement of
Technological
Comparison**

Tyber Medical Wedge System and its predicate device have the same indications for use, materials, technology and similar design, principles of operation and test results.

Conclusion

The new Tyber Medical Wedge System is substantially equivalent to the predicate device because the material, tooth profile, heights, lengths and graft volume are unchanged. The addition of the new configurations does not add a new worst case device. Given that no new worst case is introduced, the new configurations to the Tyber Medical Wedge System do not raise any additional risk to safety and effectiveness.