October 20, 2022

Tyber Medical, LLC.
Lisa Boyle
Senior Manager, Regulatory Affairs
83 South Commerce Way
Suite 310
Bethlehem, Pennsylvania 18017

Re: K221947
Trade/Device Name: Tyber Medical Staple Fixation System (various)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: September 21, 2022
Received: September 21, 2022

Dear Lisa Boyle:

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,

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K221947

Device Name

Tyber Medical Staple Fixation System (various)

Indications for Use *(Describe)*

The Tyber Medical Staple System is indicated for:
• Fracture and osteotomy fixation, joint arthrodesis hand and foot.
• Fixation of proximal tibial metaphysis osteotomy.
• Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
• Fixation of small bone fragments (i.e., small fragments of bone which are not comminuted to the extend to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and in flat bone such as the pelvis and scapula.

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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510(k) #: K221947

510(k) Summary

Prepared on: 2022-10-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Tyber Medical, LLC.
Applicant Address	83 South Commerce Way Suite 310 Bethlehem PA 18017 United States
Applicant Contact Telephone	6102957984
Applicant Contact	Ms. Lisa Boyle
Applicant Contact Email	lboyle@tybermed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tyber Medical Staple Fixation System (various)
Common Name	Staple, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number	888.3030
Product Code	JDR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K142292	DPS/BME Speed, Speed Shift, Speed Titanium, & Elite Nintinol S	JDR
K061798/K0772298	BioPro Memory Staple	JDR
K150125	DPS/BME Elite Nitinol FIxation System	JDR

Device Description Summary

21 CFR 807.92(a)(4)

The Tyber Medical Staple Fixation System consists of sterile, single use orthopedic implants and instruments. The single use bone fixation compression staples are intended to be permanently implanted. The staples are made out of Nickel Titanium (Nitinol) available in two or four legged designs with multiple combinations of bridge width, leg lengths, and cross sections to accommodate various anatomies. The staple implant applies compression across the bone segments when the staple implant legs are released from an insertion system that applies opposing forces to the staple legs to keep them parallel during implantation. The staple is provided pre-loaded on a disposable inserter.

The sterile staple kit contains all the instruments necessary for a single-staple-implantation procedure. These instruments include an inserter with a preloaded staple implant, locating pin, a drill guide for creating appropriately spaced holes and drill bits to create appropriately sized holes in the bone for staple implantation. These components will be provided in a sterilized package to accommodate a range of anatomical sites and are discarded after the procedure is complete, removing the need for any facility reprocessing.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Tyber Medical Staple System is indicated for:

- Fracture and osteotomy fixation, joint arthrodesis hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
- Fixation of small bone fragments (i.e., small fragments of bone which are not comminuted to the extend to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and in flat bone such as the pelvis and scapula.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same in both the subject and predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has similar technological characteristics as the predicate device identified above. The subject staples compare to the predicates in indications for use, material (NiTiNOL), method of operation (pre-loaded on an inserter), method of sterilization (gamma irradiation) leg length, bridge width, and design (two and 4 legged staples with teeth).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Corrosion testing per ASTM F2129 "Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices" was performed on the implants. Test results demonstrated good corrosion resistance.

Pull-out testing per ASTM F564 "Standard Specification and Test Methods for Metallic Bone Staples" was performed. Test results demonstrated substantially equivalent results to predicates.

Four-point static and dynamic bend testing per ASTM F564 "Standard Specification and Test Methods for Metallic Bone Staples" was performed. Test results showed equivalent bend stiffness to the predicate.

MRI testing as listed below was performed. Results from the test are included in the Instructions for Use.
1. Magnetically induced displacement force (ASTM F2052).
2. Magnetically induced torque (ASTM F2213).
3. MR image artifact (ASTM F2119).
4. Radio frequency induced heating (ASTM F2182).

The Tyber Medical Staple System is substantially equivalent to the predicate devices in material, basic design features, intended use, operation and performance. Any differences between the subject and predicate device are considered minor and do not raise different questions concerning safety, performance or effectiveness. From the evidence submitted in this 510(k), the subject devices are considered substantially equivalent to the predicate device.