April 3, 2026

Tyber Medical LLC.
Nicole Merlini
Regulatory Affairs Specialist
83 South Commerce Way
Suite 310
Bethlehem, Pennsylvania 18017

Re: K253042
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: November 17, 2025
Received: November 17, 2025

Dear Nicole Merlini:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253042

Please provide the device trade name(s).

Tyber Medical Trauma Screw

Please provide your Indications for Use below.

The Tyber Medical Trauma Screw System 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. Tyber Medical Trauma Screws are not for spinal use.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253042

510(k) Summary

Prepared on: 2026-04-02

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	4842744471
Applicant Contact	Mrs. Nicole Merlini
Applicant Contact Email	nmerlini@tybermed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tyber Medical Trauma Screw
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Screw, Fixation, Bone
Regulation Number	888.3040
Product Code(s)	HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K133842	Tyber Medical Trauma Screw	HWC
K192974	Tyber Medical Trauma Screw	HWC

Device Description Summary

21 CFR 807.92(a)(4)

This traditional 510(k) submission is to add screws, similar in design and dimension, to the previously cleared Tyber Medical Trauma Screws under K133842 and K192974. The Tyber Medical Trauma Screw is designed to allow compression and fixation between two adjacent bone segments. The subject screw is available with thread diameters of 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 and 7.5mm. The screw is configured to have either full thread, long thread, or short thread. The multiple thread lengths come in various options which can assist to ensure fit for various bone sizes. General trauma screws are intended for compression and fixation of bone.
In this submission, we are including an additional sterile packaging option with no change to the method of sterilization, previously cleared with K133842 and K192974.
This Submission also references Trays, which are specific to the Tyber Medical Trauma Screws.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Tyber Medical Trauma Screw System 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. Tyber Medical Trauma Screws are not for spinal use.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are similar for both the subject and predicate device(s).

Technological Comparison

21 CFR 807.92(a)(6)

A comparison of the subject devices and the predicate devices demonstrated that the Tyber Medical Trauma Screws and Trays are substantially equivalent to the previously cleared Tyber Medical Trauma Screws in regards to the intended use/indications for use, material, design, and operational principles.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Nonclinical Testing:
Comparative engineering analysis and testing to the predicate devices demonstrated substantial equivalence. The following assessments were performed:

- Torsional Strength in accordance with ASTM F543
- Driving Torque in accordance with ASTM F543
- Pullout Strength in accordance with ASTM F543
- Biocompatibility Evaluation with identical materials and manufacturing processes to the predicates cleared under K133842 and K192974 and in accordance with ISO 10993-1.
- An MR assessment was perform for magnetically induced displacement force in accordance with ASTM F2052, magnetically induced torque in accordance with ASTM F2213, RF-induced heating in accordance with ASTM F2182, and image artifacts in accordance with ASTM F2119 demonstrating that the Tyber Medical Trauma Screws are MR Conditional.
- Sterility/Packaging in accordance with ANSI/AAMI ST79, ISO 17665, ISO 11137-1, ISO 11137-2, and ISO 11737-1.

Clinical Testing:
Not Applicable.

Conclusions:
The Tyber Medical Trauma Screws described in this submission have the same intended use, material, and manufacturing processes as the predicate devices. The additional screws and Trays (Caddy) have similar technological characteristics and indications for use as the previously cleared predicate devices. The engineering analysis and testing demonstrates the performance of the subject devices is equivalent to the predicate devices.