



December 31, 2025

Tyber Medical LLC  
Stacie Geffner-Atiya  
Senior Regulatory Affairs Specialist  
83 South Commerce Way, Suite 310  
Bethlehem, Pennsylvania 18017

Re: K252901

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, HTN  
Dated: December 23, 2025  
Received: December 23, 2025

Dear Stacie Geffner-Atiya:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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](mailto: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.

K252901

?

Please provide the device trade name(s).

?

Tyber Medical Trauma Screw

Please provide your Indications for Use below.

?

The Tyber Medical Trauma Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of bones appropriate for the size of the devices. Screws are intended for single use only. The 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)

?

## 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	201-923-0943
Applicant Contact	Ms. Stacie Geffner-Atiya
Applicant Contact Email	satiya@tybermed.com

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Tyber Medical Trauma Screw
Common Name	Bone Compression Screw
Classification Name	Smooth or threaded metallic bone fixation fastener, Single/multiple component metallic bone fixation appliances and accessories.
Regulation Number	888.3040, 888.3030
Product Code(s)	HWC, HTN

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K153575	Tyber Medical Trauma Screw	HWC
K192975	Tyber Medical Trauma Screw	HWC

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

This traditional 510(k) submission adds configurations of the previously cleared Tyber Medical Trauma Screws under K192975 and K153575. The Tyber Medical Trauma Screw is designed to allow compression and fixation between two adjacent bone segments. The screw is available with thread diameters of 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 8.0, and 9.0mm. 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. This Submission also references Washers and Trays. The Trays are specific to the Tyber Medical Trauma Screws.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Tyber Medical Trauma Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of bones appropriate for the size of the devices. Screws are intended for single use only. The 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).

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

### Nonclinical Testing:

- Comparative engineering analysis demonstrated substantial equivalence to the predicate devices ••• (K153575, K192975) for the previously conducted mechanical testing.
- The biocompatibility evaluation of the subject device leveraged equivalence in materials and manufacturing to previously cleared implants (K153575, K192975).

### Clinical Testing:

Not Applicable.

### Conclusions:

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