April 3, 2026

TW Medical
℅ Tyler Ting
Regulatory Director
Rook Quality Systems
1155 Mount Vernon Hwy
Dunwoody, Georgia 30338

Re: K254060
Trade/Device Name: Life Saving Tourniquet
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: December 17, 2025
Received: December 17, 2025

Dear Tyler Ting:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

RACHEL E. NEUBRANDER -S

for Katherine Trivedi
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254060

Device Name
Life Saving Tourniquet

Indications for Use *(Describe)*
The LST – Life Saving Tourniquet is indicated for battlefield and trauma situations to:
- Control difficult bleeds in the inguinal area.
- Control difficult bleeds in the axilla area.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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In accordance with 21 CFR 807.92 the following summary information is provided:

Contact Details

21 CFR 807.92(a)(1)

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Date Prepared: 11 DEC 2025

Device

21 CFR 807-92(a)(2)

Trade Name:	Life Saving Tourniquet (LST)
Common Name:	Life Saving Tourniquet (LST)
Classification Name:	Vascular Clamp
Regulatory Class:	II
Product Code(s):	DXC
Regulation Number:	870.4450
Classification Panel:	Cardiology

Predicate Device

21 CFR 807.92(a)(3)

Tsadik-Weiser Medical, Ltd. submits the following information to demonstrate that the subject device LST – Life Saving Tourniquet, is substantially equivalent to the following legally marketed predicate device:

510(k) Number	Name	Product Code
K131561	SAM Junctional Tourniquet	DXC

Device Description

21 CFR 807.92(a)(4)

The LST – Life Saving Tourniquet is designed to effectively control severe bleeding in emergency situations by compressing the artery and maintaining continuous pressure during evacuation. The device is comprised of a durable handle, inner strap, sturdy buckle, dedicated bridge, pressure pin, and "cut here" section for easy application and evaluation. See Figure 1 below for device components. For junctional injuries, the LST is positioned so that the pressure pin applies force on the main artery leading to the limb. The strap is then tightened holding the pin firmly in place.

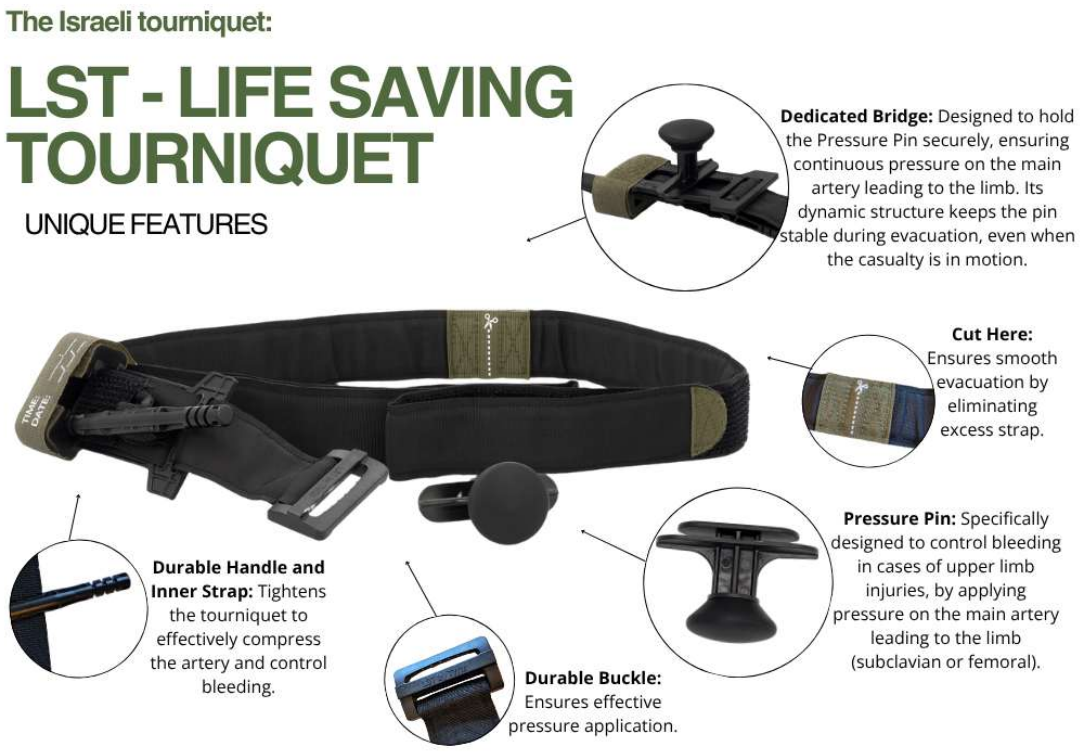

Figure 1: LST - Life Saving Tourniquet component diagram

Indications for Use

21 CFR 807.92 (a)(5)

The LST – Life Saving Tourniquet is indicated for battlefield and trauma situations to:

- Control difficult bleeds in the inguinal area.
- Control difficult bleeds in the axilla area.

Comparison of Technological Characteristics with the Predicate Device

21 CFR 807.92 (a)(6)

The subject device has the same intended use, indications, principle of operation, similar technological and material characteristics as the predicate device, SAM Junctional Tourniquet (K131561). Comparisons of the devices can be found in Table 1:

Table 1 Comparison of the Subject, Primary Predicate, and Reference Devices

	This 510(k) Notification **The LST – Life Saving Tourniquet** **(Subject Device)**	**SAM Junctional Tourniquet** **(Predicate Device)** **K131561**	**Discussion**
Product Code, Device Risk Classification	DXC Class II	DXC Class II	Identical
Indications for Use	The LST - Life Saving Tourniquet is indicated for battlefield and trauma situations: • To control difficult bleeds in the inguinal area. • To control difficult bleeds in the axilla area	The SAM Junctional Tourniquet (SJT) is indicated for battlefield and trauma situations: • To control difficult bleeds in the inguinal area. • To control difficult bleeds in the axilla area. • To immobilize a pelvic fracture.	Substantially Equivalent – The subject device is indicated for junctional use in trauma and battlefield situations to control bleeding in the inguinal and axilla areas. The subject device does not include the additional pelvic fracture immobilization indication of the predicate. The subject device has a narrower indication for use.
Risk Classification	II	II	Identical
Regulation Number	21 CFR 870.4450	21 CFR 870.4450	Identical
Regulation Name	Vascular Clamp	Vascular Clamp	Identical

Intended Use Environment	Battlefield and trauma situations	Battlefield and trauma situations	Identical
Target Population	Adults	Adults	Identical
Rx or OTC	Rx only	Rx only	Identical
Mode of Operation	Buckle the tourniquet in place and use the handle to wind to apply additional pressure.	Buckle the tourniquet in place and use the hand pump to inflate the TCD until hemorrhage stops.	Substantially Equivalent - both the subject and predicate device use a buckle to secure the device and a manual mechanism for applying pressure. The subject device uses a handle to wind additional pressure, and the predicate uses a hand pump to inflate a TCD.
Pressure Point Mechanism	Manual, Non-pneumatic pressure pin	Manual, pneumatic	Substantially Equivalent - both the subject and predicate devices utilize a manual pressure point mechanism. The subject device is a mechanical pressure pin and the predicate is a manual pneumatic mechanism.
Shelf Life	N/A	N/A	Identical
Sterility	Nonsterile, single use	Nonsterile, single use	Identical

Biocompatibility

The device is intended for limited contact with intact skin. The device materials and intended use meet the requirements of Attachment G: Biocompatibility of Certain Devices in Contact with Intact Skin of FDA guidance document Use of International Standard ISO 10993-1 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Performance Data

Bench

Non-clinical validation testing was performed to demonstrate the substantial equivalence of the device to the predicate. The following tests were performed:

- Usability
- Pressure Retention Testing
- Effectiveness During Evacuation

Animal

No animal or clinical testing was performed in support of this submission.

Clinical

No animal or clinical testing was performed in support of this submission.

Substantial Equivalence Conclusion

Based on the comparison of indication of use, material characteristics, technological features, and principle of operation, the LST – Life Saving Tourniquet is substantially equivalent to the predicate device.