November 18, 2024

Trice Medical, Inc.
David Vancelette
VP of Quality Assurance & Regulatory Affairs
40 General Warren Blvd.
Suite 100
Malvern, Pennsylvania 19355

Re: K241700
Trade/Device Name: Tenex 2nd Generation System
Regulatory Class: Unclassified
Product Code: LFL
Dated: June 11, 2024
Received: June 13, 2024

Dear David Vancelette:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.11.18 15:01:04 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
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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)*
K241700

Device Name
Tenex® 2nd Generation System

Indications for Use *(Describe)*
The Tenex® 2nd Generation System is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of both soft and hard (e.g.: bone) tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery, and Plastic and Reconstructive Surgery.

The Tenex® 2nd Generation System is also indicated for use in the debridement of wounds, such as, but not limited to diabetic ulcers, in application, in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date: November 7, 2024

Owner:
Trice Medical, Inc.
40 General Warren Blvd.
Suite 100
Malvern, PA 19355 USA
Phone: (610) 989-8080
www.tricemedical.com

Contact Person:
David Vancelette
Vice President of Quality Assurance & Regulatory Affairs
P: 949-238-8220
E: dvancelette@tricemedical.com

Type of 510(k) Submission: Traditional

Trade Name: Tenex® 2nd Generation System

Common Name: Ultrasonic Surgical Instrument

Classification Name: Instrument, Ultrasonic Surgical

Device Class: Unclassified

Panel: General & Plastic Surgery

Product Code: LFL

Predicate Devices: K181367, Tenex Health TX System with the TXP MicroTip, Product Code: LFL

Device Description:

The Tenex 2nd generation system is an ultrasonic surgical instrument that fragments, emulsifies and aspirates soft and hard tissue. It also provides sharp debridement of soft and hard tissue in wounds such as neuropathic diabetic ulcers. The Tenex 2nd generation system is intended for use in an office-based setting, clinical or hospital environment. The system consists of a Console, ultrasonic MicroTips, a Foot Switch and a number of accessories.

The Console includes a touch screen tablet with a graphical user interface, motors to drive diaphragm pumps in the MicroTip, ultrasonic driver electronics and Software. The Console generates the ultrasonic energy required to operate the MicroTips and manages irrigation and aspiration fluids. The Console is non-sterile when used and does not require processing.

The MicroTips connect to the Console for electrical power and to facilitate the transfer of irrigation fluid from the saline bag to the surgical site, and then aspirate the emulsified tissue and fluid to a collection bag incorporated into single use, disposable the MicroTip assembly. Motors in the Console couple to the diaphragm pumps in the MicroTips to control the fluid flows. The MicroTips are constructed from

various biocompatible polymers and metals. The MicroTip tubing is made of biomedical grade PVC and silicone.

The MicroTips are single use and sterile packaged. They are sterilized via gamma irradiation. The MicroTips are the ultrasonic surgical hand pieces that house the transducers, horns and needles with beveled tips.

The Foot Switch is used by the user to remotely control the function of the Console. It connects to the back of the Console via an electrical cable. It provides on/off functionality for cutting, irrigation, and aspiration. The Foot Switch is IPX8 rated for protection against liquids.

The System includes additional components. a Packaging Hard Case is provided for shipping, handling, and storage of the Console, and a power cord is provided for connecting the Console to facility electrical power to operate the device. These items are non-sterile when used and do not require processing.

Associated accessories include: a USB Flash Drive for saving procedure information, USBC-HDMI cable for connecting to an external display, and a USB-Smartphone adaptor for connecting USB output to a smartphone.

Intended Use / Indications for Use:

The Tenex® 2nd Generation System is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of both soft and hard (e.g.: bone) tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery, and Plastic and Reconstructive Surgery.

The Tenex® 2nd Generation System is also indicated for use in the debridement of wounds, such as, but not limited to diabetic ulcers, in application, in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement.

Technical Characteristics (Compared to Predicate):

The subject and predicate devices are ultrasonic surgical instruments that use electrical energy in the ultrasonic frequency range to drive an applicator needle for the fragmentation and emulsification of diseased tissue. The systems use irrigation with the needle at the treatment site to emulsify the fragmented tissue. The systems also use aspiration to remove the fragmented and emulsified material from the treatment site.

The following technological characteristics are identical for the subject and predicate device:

Characteristic	**Subject Device** **Tenex® 2nd Generation System**	**Predicate Device** **Tenex Health TX System with TXP MicroTip (K181367)**
Energy source	100-240V 50/60Hz	Same
Fragmentation/ Emulsification	Ultrasonic energy	Same
Vibration system	Piezoelectric	Same
Frequency	26.5 ±1.5kHz	Same
Aspiration	Vacuum	Same

Characteristic	**Subject Device** Tenex® 2nd Generation System	**Predicate Device** Tenex Health TX System with TXP MicroTip (K181367)
Irrigation	Forced	Same
System Control	Foot switch	Same
MicroTip Horn/Needle	One-piece, stainless steel	Same
Tip sheaths	Stainless steel sheath	Same
Reusable System Components	Console and Foot Switch	Same

The following technological characteristics of the subject device and predicate were compared and found to have differences which do not affect the mode of operation:

Characteristic	**Subject Device** Tenex® 2nd Generation System	**Predicate Device** Tenex Health TX System (K181367)	Comparison
Cutting levels	User selected: low, medium and high	Same	Updated ultrasonic driver
Irrigation flow control	User controllable, forced delivery of saline from an external saline bag	Same	Using a fluid pump instead of a pressure cuff
Irrigation flow rates	In excess of 60 cc/min	In excess of 30 cc/min with a full 1000cc saline irrigation bag.	Enhanced to stabilize flow rate
Aspiration flow control	User controllable, suction provided by a vacuum pump	Same	Enhanced the pump
Aspiration flow rates	User selectable, 3 levels between 100-200 cc/min	User selectable, 3 levels between 10-30 cc/min	Enhanced to improve occlusion prevention and removal
Aspiration potential (vacuum pressure)	User selectable, 3 levels between 0 - 520mmHg	User selectable, 3 levels between 100 - 500 mmHg	Enhanced to improve time to vacuum pressure and occlusion prevention.
Aspiration Waste Container	1000cc sterile collection bag integrated into the MicroTip	1000cc sterile collection bag integrated into the MicroTip	Subject device incorporates additional filtration.
MicroTip Case Nose	ABS over-molded stainless-steel sheath	Polycarbonate over-molded stainless-steel sheath	Both have equivalent biocompatible polymer over-molding
Tip diameters	Multiple MicroTips, between 1.5 - 1.9mm (.059 - .074 in)	Multiple MicroTips, between 1.1 - 1.9mm (.042 - .074 in)	Improved tip strength and durability.
Tip lengths	Multiple MicroTips, between 1.0 - 3.0 in	Multiple MicroTips, between 1.0 - 2.0 in	Improved depth of reach.

Characteristic	**Subject Device** Tenex® 2nd Generation System	**Predicate Device** Tenex Health TX System (K181367)	Comparison
Single-Use, Sterile Components	MicroTips	MicroTips Supply Kit	Convenience kit removed
User Interface	Color touchscreen, component of an internal MS Tablet	Color touchscreen, connected to the internal computer.	Higher resolution, greater processing power for more display and interface features.
Software/Firmware	Windows Operating System running Application Software on Touch Screen Tablet, interfaces with Firmware on DSP Microcontroller	Linux Operating System running Application Software on ARM Microprocessor	Improved programming, display and interface options with current technology
Ultrasonic driver	Digital Voltage and Frequency Controlled	Analog Frequency Controlled	Enhanced control of power and acoustics

Non-Clinical Performance Data:

The following non-clinical performance tests were conducted to evaluate differences noted above and demonstrate substantial equivalence to the predicate device:

1) Electro-mechanical bench testing verified that the system met requirements for:
   - Aspiration
   - Irrigation
   - Cassette attachment and detection
   - Console functions
   - Console life cycle
   - Environmental operating conditions
   - Hardware verification
   - MicroTip functions
   - MicroTip strength
   - Transit conditions

2) EMC and electrical safety testing verified the system met the standards:
   - IEC 60601-1:2005+A1:2012+A2:2020 / Edition 3.2 2020-08 Consolidated Version, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
   - IEC 60601-1-2:2014+A1:2021, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

3) Software Verification & Validation …

- Software was developed, verified and validated per IEC 62304:2006/A1:2016, Medical device software - Software life cycle processes

4) Biocompatibility evaluation verified the system met the standard: ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

5) Sterilization validation of the sterile packaged MicroTip showed the device met the standards:
   - ISO 11137-1 Third edition 2018-01 [Including AMD1:2021], Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
   - ISO 11137-2 Third edition 2013-06 [Including AMD1:2022], Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

6) Packaging & Shelf Life Validation of the sterile packaged MicroTip showed the device met the standards:
   - ISO 11607-1 Second edition 2019-02 [Including AMD1:2023], Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
   - ISO 11607-2 Second edition 2019-02, Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

7) Simulated use testing in bovine tissue
   - Validated the system's performance and durability in tissue.

8) Simulated use testing in cadaver validated the system's design and usability.
   - Usability Validation per IEC 60601-1-6 Edition 3.2 2020-07 Consolidated Version, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability, and:
   - ANSI AAMI IEC 62366-1:2015+AMD1:2020 Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
   - Cadaveric design validation of the device in a simulated surgical setting for its Indications for Use.

Conclusions:

The Tenex® 2nd Generation System met all specified performance requirements. The non-clinical data, including the simulated use testing results, demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device. Evaluation did not raise any new questions regarding safety and effectiveness. The Tenex® 2nd Generation System is determined to be substantially equivalent to the predicate device.