August 28, 2018

Tenex Health, Inc.
Mr. David Vancelette
Vice President of QA/RA
26902 Vista Terrace
Lake Forest, California 92630

Re: K181367
Trade/Device Name: Tenex Health TX System
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 22, 2018
Received: May 23, 2018

Dear Mr. 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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181367

Device Name
Tenex Health TX System with the TXP MicroTip

Indications for Use *(Describe)*
The Tenex Health TX System with the TXP MicroTip 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 Health TX System with the TXP MicroTip 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.

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510(k) Summary

A 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

Date: August 25, 2018

Submitter:
Tenex Health, Inc.
26902 Vista Terrace
Lake Forest, CA 92630
Phone: 949-454-7500
Fax: 949-580-1270

Official Correspondent:
David Vancelette
Vice President of Quality Assurance & Regulatory Affairs
Phone: 949-238-8220
Email: dvancelette@tenexhealth.com

Type of Submission: Traditional 510(k). The Tenex Health TX System with the TXP MicroTip is a modification to the previously cleared Tenex Health TX System (K153299).

Trade Name: Tenex Health TX System with the TXP MicroTip

Common Name: Ultrasonic Surgical Instrument

Device Class: Unclassified

Panel: General & Plastic Surgery

Product Code: LFL

Classification Name: Instrument, Ultrasonic Surgical

Predicate Devices: Ultrasonic Surgical Aspirator System Model FS 1000 RF (K062471)

AUSS-6 Ultrasonic Surgical Aspirator System and Accessories (K050776)

The Tenex Health TX System (K153299) is a reference device with regard to the device assembly process and technological characteristics.

Device Description:

The Tenex Health TX System with the TXP MicroTip 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 ulcers. The Tenex Health TX System with the TXP MicroTip is intended for use in an office-based setting, clinical environment or hospital environment. The system consists of a console, ultrasonic MicroTip, inflation cuff, foot pedal and supply kit. The console provides power and control for the user functions including irrigation, aspiration, and ultrasonic fragmentation/emulsification. It has a large, color LCD and employs a touch-screen with a graphical user interface for selection of required settings. The console provides audible tones for confirmation of

selections. The console also houses the irrigation valve, the irrigation pump and the aspiration pump. The Console is non-sterile when used and does not require processing.

The ultrasonic MicroTip connects to the console for electrical power, the transfer of irrigation fluid to the surgical site and the aspiration of emulsified tissue back to the collection bag. The MicroTip is single use, sterile packaged. A single use, disposable collection bag is integrated into the MicroTip tubing to collect the aspirated materials. The connections are made via an integrated wiring connector and tubing set. The handpiece is constructed from various biocompatible polymers and metals. The tubing is made of biomedical grade PVC. The handpiece and tubing are provided sterile, via electron beam irradiation. The handpiece and tubing are a single use disposable component of the system. Irrigation fluid is delivered from a user-provided surgical saline bag, under pressure to the surgical site by operation of an air pump residing in the console. The regulated output of the air pump pressurizes an inflation cuff that is fitted over the saline bag.

The foot pedal 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 and is rated IPX8 for protection against liquids.

The System also includes accessories. A Travel Case is provided for shipping, handling and storage of the TX Console. A power cord is provided for connecting the Console to facility electrical power in order to operate the device. A replacement fuse set is also provided in case of the need for replacement of electrical fuses in the TX Console. The accessories are non-sterile when used and do not require processing.

The supply kit contains sterile packaged, single use, OEM surgical supply items for use in the surgical site preparation and closure. These include a syringe and needle, scalpel, an ultrasound probe cover, gauze, closure strips and dressing. The itemized contents of the kit with their manufacturer and regulatory information are provided in Table 4 below.

The Tenex Health TX System with the TXP MicroTip is an upgrade to the Tenex Health TX System (K153299), with the addition of the TXP MicroTip, an upgraded handpiece with indications for use for the treatment of hard tissue and the sharp debridement of wounds such as neuropathic ulcers.

Indications for Use:

The Tenex Health TX System with the TXP MicroTip 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 Health TX System with the TXP MicroTip 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.

The Tenex Health TX System with the TXP MicroTip has the same Indications for Use as the reference device, existing Tenex Health TX System (K153299), for the fragmentation, emulsification, and aspiration of soft tissue in general surgery, orthopedic surgery, laparoscopic surgery and plastic and reconstructive surgeries.

The Tenex Health TX System with the TXP MicroTip has the same Indications for Use as the predicate Ultrasonic Surgical Aspirator System FS1000RF (K062471) for the fragmentation, emulsification, and aspiration of soft and hard (e.g.: bone) tissue in general surgery, orthopedic surgery, laparoscopic surgery and plastic and reconstructive surgeries.

The Tenex Health TX System with the TXP MicroTip has the same Indications for Use as the predicate AUSS-6 Ultrasonic Surgical Aspirator System and Accessories (K050776) for both the fragmentation, emulsification, and aspiration of soft and hard (e.g.: bone) tissue in general surgery, orthopedic surgery, laparoscopic surgery and plastic and reconstructive surgeries; and for the debridement of wounds, such as diabetic ulcers, in application, in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement. This Indication is a specific application of the same device performance to treat soft and hard tissue pathology. Simulated clinical use testing in this submission demonstrates the Tenex Health TX System with the TXP MicroTip to be safe and effective in this Indication.

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, predicate and reference devices:

Characteristic	**Subject Device** **Tenex Health TX System with the TXP MicroTip**	**Predicate Device** **Ultrasonic Surgical Aspirator System FS1000RF (K062471)**	**Predicate Device** **AUSS-6 Ultrasonic Surgical Aspirator System (K050776)**	**Reference Device** **Tenex Health TX System (K153299)**
Energy source	100-240V 50/60Hz	Same	Same	Same
Fragmentation/ emulsification	Ultrasonic energy	Same	Same	Same
Vibration system	Piezoelectric	Same	Same	Same
Aspiration	Vacuum	Same	Same	Same
Irrigation	Forced	Same	Same	Same
System Control	Foot pedal	Same	Same	Same

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

Character-istic	**Subject Device** Tenex Health TX System with the TXP MicroTip	**Predicate Device** Ultrasonic Surgical Aspirator System FS1000RF (K062471)	**Predicate Device** AUSS-6 Ultrasonic Surgical Aspirator System (K050776)	**Reference Device** Tenex Health TX System (K153299)	Comments
Power delivery	Constant (user selected duty cycles of low, medium, and high)	Variable - user controlled	Variable - user controlled	Same as subject device	Electronic console is identical to that of reference device K153299
Irrigation flow control	Forced, via air pressurization of an inflation cuff (for external saline bag)	Forced, via peristaltic pump, flow rate control knob	Forced, via peristaltic pump, flow rate control knob	Same as subject device	Same functionality
Irrigation flow rates	Free-flow (in excess of 30 cc/min) with a full 1000cc saline irrigation bag.	Variable: 2-25 cc/min	Variable: 0-300 mL/min	Free-flow (in excess of 30 cc/min) with a full 500cc saline irrigation bag.	
Aspiration flow control	Vacuum pump, solenoid pinch valves, 3 user selectable levels on a touchscreen GUI	Vacuum pump, valves, pressure level readout	Vacuum pump, valves, pressure level readout	Same as subject device	
Aspiration flow rates	Constant (user selectable levels of 10cc/20cc/30cc/ min)	Variable, limited by irrigation flow rate during operation, 2-25 cc/min	Variable, limited by irrigation flow rate during operation	Same as subject device	
Aspiration potential (vacuum pressure)	Adjustable: 100 mmHg, 300 mmHg or 500 mmHg	Adjustable: 75 -585 mmHg	Variable: 75-508 mmHg	Same as subject device	
Aspiration Waste Container	1000cc sterile collection bag integrated into the MicroTip (affixed to cartridge)	2 liter sterile fluid containment bag	2 liter sterile fluid containment bag	500cc sterile collection bag integrated into the MicroTip (affixed to cartridge)	
Frequency	26.5 ±1.5kHZ	22.5kHz±500Hz	22.5kHz±500Hz	Same as subject device	
MicroTip Case Nose	Polycarbonate over-molded stainless steel sheath	Polycarbonate front housing component	Polycarbonate front housing component	Same as subject device	

Character-istic	**Subject Device** Tenex Health TX System with the TXP MicroTip	**Predicate Device** Ultrasonic Surgical Aspirator System FS1000RF (K062471)	**Predicate Device** AUSS-6 Ultrasonic Surgical Aspirator System (K050776)	**Reference Device** Tenex Health TX System (K153299)	Comments
MicroTip Horn/Needle	One-piece, stainless steel, 14 gage needle, 1.6mm ID	Various sizes of stainless steel or titanium tips, including 1.1mm and 1.6mm ID needle tips and a 1.8mm ID bone shaving tip. Separate stainless steel horn internal to the handpiece.	Various sizes of stainless steel or titanium tips. Separate stainless steel horn internal to the handpiece.	Two stainless steel pieces brazed together, 18 gage needle, 0.8mm ID	Various size needle tips are appropriate for soft and hard tissue. K062471 includes 3 comparably sized tips. The single horn/needle assembly provides an equivalent final construction.
Tip length	1.29”	Variable: 3” – 11.8”	Variable: 3” – 11.8”	1.74”	Longer tips are for laparoscopic application, not applicable to subject device’s indications.
Distal Tip shape	Cylindrical	Cylindrical	Various, including Cylindrical	Same as subject device	
Tip sheath	Stainless steel sheath	Silicone rubber sheath	Various, depending on probe tip	Same as subject device	Both sheaths provide contained channel for irrigation. Subject device has a durable hard plastic sheath for percutaneous application
Reusable System Components	Console (generator), saline inflation cuff	Console, (generator), handpiece, handpiece front housing and wrenches	Console, (generator), handpiece, handpiece front housing and wrenches	Same as subject device	

Character-istic	**Subject Device** Tenex Health TX System with the TXP MicroTip	**Predicate Device** Ultrasonic Surgical Aspirator System FS1000RF (K062471)	**Predicate Device** AUSS-6 Ultrasonic Surgical Aspirator System (K050776)	**Reference Device** Tenex Health TX System (K153299)	Comments
Single-Use, Sterile Components	TX-Plus MicroTip (tip, integrated sheath, handpiece and tube set), fluid containment bag and Supply Kit Components	Probe tip, sheath, tube set and fluid containment bag	Probe tip, sheath, tube set and fluid containment bag	Same as subject device	
MicroTip Supply Kit	Commercially available medical supplies manufactured by other manufacturers	None provided	None provided	Same as subject device	Supply Kit is identical to that of reference device K153299

Performance Data:

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

1) Electro-mechanical bench testing verified that the system met requirements for:
   - Aspiration vacuum
   - Automated priming
   - Irrigation flow
   - Aspiration volume
   - Operating frequency
   - Operating temperatures
   - Needle stroke length
   - MicroTip pull strength
   - Inflation cuff pressurization
   - Collection bag performance
   - Corrosion resistance
   - Primary acoustic output area
   - Output acoustic power

2) EMC and electrical safety testing verified the system met the standards:
   - IEC 60601-1:2005 + A1 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Edition 3.1.

- IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests – Edition 4.0.

3) Biocompatibility evaluation verified the system met the standard: ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

4) Sterilization validation of the sterile packaged MicroTip showed the device met the standards:

   - ANSI/AAMI/ISO TIR13004:2013, "Sterilization of health care products – Radiation – Substantiation of a selected sterilization dose: Method VD_{max} ^{SD}.
   - ISO 11137-1:2013, Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

5) Packaging Validation of the sterile packaged MicroTip showed the device met the standards:

   - ISO 11607-1:2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
   - ISO 11607-2:2006, Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

6) Simulated use testing in cadaver validated the system's design, usability and surgical technique.

   Simulated use testing involved use of the device in a simulated surgical setting with cadaveric evaluation by three surgeon advisors. Testing validated the instruction steps in the product labeling, usability (human factors) and the effectiveness of the system in sharp debridement of soft and hard tissue in wounds, such as diabetic foot ulcers.

7) Simulated use testing in bovine tissue validated the system's durability and ability to cut, fragment, emulsify and aspirate tissue as effectively as the predicate device. Testing also quantified the tissue removal rates in both soft and hard tissue.

   The testing involved multiple sample devices, both soft and hard bovine tissue media, actuation of all system functions (fragmentation/ emulsification, irrigation and aspiration), performance at each power setting (low, medium and high) and extended use of the device. Testing demonstrated the effectiveness of all system functions at all settings for performance in both soft and hard tissue, and provided quantitative data for tissue removal rates in soft and hard tissue.

Conclusions:

The Tenex Health TX System with the TXP MicroTip met all specified performance requirements. The non-clinical data, including the simulated use testing results, support the safety of the Tenex Health TX System with the TXP MicroTip, and demonstrate that it should perform as intended in the specified use conditions. Evaluation did not raise any new questions regarding safety and effectiveness. The Tenex Health TX System with the TXP MicroTip is determined to be substantially equivalent to the predicate devices.