DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 3, 2016

Tenex Health, Inc.
Ms. Gloria Pendergrass
Regulatory Affairs
26902 Vista Terrace
Lake Forest, CA 92630

Re: K153299
Trade/Device Name: Tenex Health TX System
Regulation Name: Instrument, Ultrasonic Surgical
Regulatory Class: Unclassified
Product Code: LFL
Dated: February 5, 2016
Received: February 8, 2016

Dear Ms. Pendergrass:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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)*
K153299

Device Name
Tenex Health TX System

Indications for Use *(Describe)*
The Tenex Health TX System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

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.

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510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) – Submitter information	
Name	Tenex Health, Inc.
Address	26902 Vista Terrace, Lake Forest, CA 92630 USA
Phone Number	949-454-7500
Fax Number	949-580-1270
Establishment Registration Number	3009750704
Name of Contact Person	Gloria Pendergrass
Date Prepared	February 29, 2016
807.92(a)(2) – Name of Device	
Trade or Propriety Name	Tenex Health TX System
Common or Usual Name	Ultrasonic Surgical Aspirator
Classification Name	Instrument, Ultrasonic Surgical
Classification Panel	General and Plastic Surgery
Regulation	Unclassified
Product Code(s)	LFL
807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
TX1 Tissue Removal System K123640	
807.92(a)(4) – Device description	
The Tenex Health TX System is an ultrasonic surgical aspirator that fragments, emulsifies and removes soft tissue. The system consists of a console, ultrasonic handpiece, inflation cuff and foot pedal. The console provides control over 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, thereby eliminating the need for a dedicated service cart or suction/waste source within the operating room. The ultrasonic handpiece connects to the console for power, as well as for delivering irrigation fluid directly to the surgical site and for aspirating emulsified tissue by way of integrated tubing set. The handpiece is constructed from various polymers and metals, while the tubing is made of biomedical grade PVC. The handpiece and tubing are provided sterile. The handpiece and tubing are a single use disposable component of the system. Irrigation fluid is delivered 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 filled around the irrigating fluid bag, thus providing irrigation at a fixed pressure.	

<table>
<tr><td colspan="3">The foot pedal is used to control each of the functions (irrigation, aspiration, ultrasonic fragmentation/emulsification) of the system. It offers on/off functionality and is rated IPX8 (by the supplier) for protection against liquids.</td></tr>
<tr><td colspan="3">807.92(a)(5) – Intended use of the device</td></tr>
<tr><td>Indications for Use</td><td colspan="2">The Tenex Health TX System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.</td></tr>
<tr><td colspan="3">807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate</td></tr>
<tr><td colspan="3">The Tenex Health TX System is identical to the predicate TX1 Tissue Removal System in its mode of operation and Indications for Use. Specifically, the following areas were compared and found to have similar technological characteristics and to be equivalent:</td></tr>
<tr><td>Device Characteristics</td><td colspan="2">Similarities between Tenex Health TX System and TX1 Tissue Removal System</td></tr>
<tr><td>Mode of Operation</td><td colspan="2">• Method of tissue emulsification (ultrasonic energy)
• Method of aspiration (vacuum)
• Aspiration flow (10cc/20cc/30cc per minute)
• Method of irrigation (forced)
• Control (foot pedal)</td></tr>
<tr><td>MicroTip</td><td colspan="2">• Material in contact with tissue (304 SS, polycarbonate)
• Frequency (26.5±1.5KHz)
• Vibration system (piezo)
• Power source (100-240V, 50/60Hz)
• Shelf-life (12 months)
• Sterility (E-beam radiation)
• Single use, disposable</td></tr>
<tr><td>Console</td><td colspan="2">The same console may be used with the predicate device TX1 MicroTip or the modified TX2 MicroTip</td></tr>
<tr><td>Convenience Kit</td><td colspan="2">Supply kit containing commercially available devices designed/ manufactured by other manufacturers</td></tr>
<tr><td colspan="3">The Tenex Health TX System and the predicate TX1 Tissue Removal System were compared in the following areas and found to have minor different technological characteristics:</td></tr>
<tr><td rowspan="2">Device Characteristics</td><td colspan="2">Differences</td></tr>
<tr><td>Subject Device:
Tenex Health TX System</td><td>Predicate Device:
TX1 Tissue Removal System</td></tr>
<tr><td>Technology/TX System Functions</td><td>Technology is based on ultrasonic surgical aspiration, which may perform the following functions: Irrigation, aspiration, ultrasonic fragmentation/emulsification.</td><td>Technology is based on ultrasonic surgical aspiration, which may perform the following functions: Irrigation, aspiration, ultrasonic</td></tr>
</table>

		fragmentation/emulsification, coagulation
MicroTip Needle	Brazed; 18 gage; 2.3" overall needle length and extend 1.7" from the ultrasonic horn	Brazed; 19 gage; 1.3" overall needle length and extend 1" from the ultrasonic horn
MicroTip Case Nose	TX2 is comprised of a molded polycarbonate case nose and a 304 SS sheath	TX1 is comprised entirely of a molded polycarbonate sheath
807.92(b)(1-2) – Nonclinical and clinical tests submitted		
The Tenex Health TX System has been designed and tested to pass the following non-clinical performance tests:		
Performance Characteristic Verification	• stroke length determination • ultrasonic frequency • aspiration vacuum • irrigation flow (free flow) • irrigation flow (aspiration volume) • operating frequency • device operating temperature	
Functional Verification (under simulated use)	• automated priming, durability verification • pull strength of metal sheath • effectiveness of TX2 MicroTip to fragment, emulsify and remove soft tissue in comparison to the TX1 MicroTip	
Design Validation (under simulated use)	• Functional validation	
The Tenex Health TX System has been designed to conform to the following Voluntary Standards:		
EMC and General Electrical Safety	• IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	
Performance	• IEC 61847 Ultrasonic – Surgical systems – Measurement and declaration of the basic output characteristics	
Biocompatibility	• ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	
Sterilization	• ISO 11137-1 Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices • ISO 11737-1 Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	

	• ISO 11737-2 Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
Packaging	• ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems • ISO 11607-2 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

807.92(b)(3) – Conclusions drawn from non-clinical and clinical data

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

It has been shown in this 510(k) submission that the difference between the Tenex Health TX System and the predicate device, the TX1 Tissue Removal System, does not raise any questions regarding its safety and effectiveness. The Tenex Health TX System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.