DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 13, 2016

Acoustic Medsystems Incorporated
Ms. Yvonne Schleife
Regulatory and Quality Systems Manager
208 Burwash Avenue
Savoy, Illinois 61874

Re: K150019
Trade/Device Name: TheraVision Ultrasound Ablation System and ACOUSTx Applicators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NTB
Dated: November 23, 2015
Received: November 30, 2015

Dear Ms. Schleife:

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 Industry and Consumer Education 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 Industry and Consumer Education 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 -S

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)*
K150019

Device Name
TheraVision Ultrasound Ablation System and ACOUSTx Applicators

Indications for Use *(Describe)*
The TheraVision Ultrasound Ablation System, ACOUSTx Applicators, and accessories are intended for the laparoscopic, intraoperative, and percutaneous coagulation and ablation of soft tissue. It is not indicated for ablation of prostate tissue.

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

1.0 Submitter Information

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Date summary prepared: 16 November 2015

2.0 Name of Device

Trade Name: TheraVision™ Ultrasound Ablation System and ACOUSTx™ Applicators

Common/Classification Name: Electrosurgical cutting and coagulation device and accessories

Regulation Number: 878.4400

Device Class: II

Product Code: NTB

Reason for submission: New Device

K Number: K150019

3.0 Predicate Devices

The TheraVision System and ACOUSTx Applicators are substantially equivalent to the following legally marketed devices:

- Sonatherm 600i Ultrasonic Lesion Generating System [K070779] - *Primary Predicate*
- Cool-tip™ RF Ablation System [K053290]
- Valleylab Microwave Ablation Generator and Microwave Antennas [K072687 and K011676/K032702, respectively]

4.0 Device Description

The TheraVision System consists of the following subsystems:

4.1 Computer System: The computer system consists of a PC Compatible type computer running Microsoft Windows® Operating system.

4.2 Visualization Options: Visualization options include utilization with compatible, legally marketed imaging systems. Patient images may be imported in DICOM format from MRI, CT, US, Fluoroscopic X-Ray, and PET-CT scanners.

4.3 Software: A set of user interface and display modules allow user interaction and high-level control over the system, including power generation and safety monitoring. Top-level modules provide top level menu options and implement next-generation Microsoft Windows® display functionality.

4.4 Thermometry System: Temperature monitoring is accomplished using an optional multichannel type T patient isolated thermocouple data acquisition system.

4.5 RF Generation System: A Multichannel RF power generator system provides the RF energy needed drive the piezoelectric transducers for generation of sufficient ultrasound acoustic energy from the applicators to raise the temperature to therapeutic levels in the targeted tissue

4.6 Cooling System: Degassed sterile water is pumped through the ultrasound transducers in the applicators and provides ultrasound energy coupling to tissue and also provides a means for cooling the applicator.

ACOUSTx Applicators:

The ultrasound energy generated from ACOUSTx Applicators is absorbed during treatment producing thermal therapy within the targeted tissue region. The ACOUSTx Applicators are sterile and single-use and can be utilized with the TheraVision System and may contain up to four transducers each with angular insonation patterns of 360° or 180° for application of thermal therapy.

5.0 Indications for Use

The TheraVision Ultrasound Ablation System, ACOUSTx Applicators, and accessories are intended for the laparoscopic, intraoperative, and percutaneous coagulation and ablation of soft tissue. It is not indicated for ablation of prostate tissue.

6.0 Summary of Device Characteristics

TheraVision System: The TheraVision System includes a multichannel RF power generator system, cooling pump, monitor, power supply, mouse and keyboard. The TheraVision System includes custom software with a graphic user interface (GUI) that allows users to create or adjust treatment plans, control and direct the application of ultrasound energy to targeted areas, and review the resulting treatment data. A single use sterile cooling circuit is external to the TheraVision System and connect to the circulating cooling pump, water bag and applicators. Pumping sterile room temperature water through and around the ACOUSTx Applicators is needed for ultrasonic energy coupling and also provides an effective means for cooling the ultrasound transducers during power-on operation. Optional use of an imaging device can provide additional anatomical information for device guidance and monitoring.

ACOUSTx Applicators: During treatment, single or multiple applicators may be utilized simultaneously, depending on the volume of the targeted region. ACOUSTx applicators do not directly contact the patient due to insertion within a sterile, biocompatible, legally marketed closed-tip interstitial plastic catheter. Degassed sterile water flows through an embedded channel in the applicator and the return water exits the catheter by flowing back out of the catheter on the exterior surface of the applicator within the interstitial catheter. An embedded thermocouple in each applicator is provided as a water flow sensor, and applicator operating temperature indication. One transducer of an ACOUSTx Applicator can deliver an acoustic output power of up to 20 Watts.

7.0 Safety and Performance Data

The TheraVision System, ACOUSTx Applicators and accessories were utilized to apply thermal therapy in both ex vivo and in vivo testing, confirming the device's safety and effectiveness. In vivo testing was performed using a porcine model and three tissue types were treated: liver, muscle, and kidney. Ex vivo testing was performed using 360° and 180° ACOUSTx Applicator models to apply thermal therapy to both chicken breast tissue and porcine tissue: liver, muscle, and kidney.

360° and 180° ACOUSTx Applicator models were also utilized for in vivo testing in order to apply thermal therapy between the frequency ranges of 5 to 11.5 MHz for the porcine tissue types (liver, muscle, and kidney) for different treatment times (3, 6, and 9 minutes). The following table provides a summary of the lesion pattern ranges (details provided in

submission). These results confirmed comparable ablation patterns and times with respect to the three listed predicate devices.

Table 1 – Summary: Ablation Dimension Range over Frequency Range 5-11.5 MHz at 6W acoustic power (For 3, 6, and 9 Minute Insonation Times)

Tissue & Treatment Pattern	**Pentratation Depth**	**Pattern Length [For 1,2,3, or 4 Active Transducers]**
Liver / 360°	1.4 - 3.4 cm	1.1 – 4.7 cm
Muscle / 360°	1.63 – 3.4 cm	1.2 – 4.7 cm
Kidney / 360°	1.5 – 2.7 cm	1.1 – 2.5 cm*
-	**Penetration Depth**	**Length**
Liver / 180°	1.9 – 2.8 cm	1.1 – 4.6 cm
Muscle / 180°	1.8 – 3.0 cm	1.1 – 4.6 cm
Kidney / 180°	1.6 – 2.7 cm	1.1 – 2.4 cm*

**1 or 2 active transducers longitudinally*

One to four transducers can be activated for any given ACOUSTx Applicator model and this allows the user to select different ablation pattern lengths as is most appropriate to the targeted area. Different active angular sectors provide directional control. This and other treatment tailoring allows for improved patient safety. The above ablation patterns were compared to the ablation patterns of the predicate devices (Sonatherm, Cool-tip, and Valleylab) which demonstrates the TheraVision System and ACOUSTx Applicators create comparable lesion patterns at comparable treatment times. Sonatherm penetration depth is up to 3 cm. Both ACOUSTx angular sector (180°) applicator and Sonatherm produce wedge-shaped ablation patterns. Cool-tip's ablation diameter is 2.3 – 2.6 cm at lengths of 2.6 – 3.7 cm. Valleylab's (Evident) ablation diameter is 1.8 – 3 cm at lengths of 3.9 – 5 cm. ACOUSTx 360° applicators, Cool-tip and Valleylab (Evident) all produce an ellipsoidal pattern. This data support the substantial equivalence of the TheraVision System and ACOUSTx Applicators to its predicates.

Other safety, performance, and bench testing was also conducted. Verification and validation testing included safety and performance testing of software and hardware and dosimetry testing in addition to risk evaluation and ship testing. This device was also tested to and complies with IEC 60601-1, IEC 60601-1-2, IEC 61000-3-2, and IEC 61000-3-3. The results from bench, animal, performance, and safety testing demonstrate the safety and efficacy of this device's intended use and technology, as well as its substantial equivalence to the predicates.

8.0 Conclusion

The TheraVision Ultrasound Ablation System, ACOUSTx Applicators, and accessories do not raise new questions of safety or efficacy and is substantially equivalent to the predicate devices based upon the intended use, operating characteristics, and outcomes.