September 28, 2018

Acessa Health, Inc.
Kim Rodriguez
President & CEO
7004 Bee Cave Road, Bldg. 3, Suite 200
Austin, TX 78746

Re: K181124
Trade/Device Name: Acessa ProVu System
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: HFG, OEW, IYO, ITX
Dated: August 31, 2018
Received: August 31, 2018

Dear Kim Rodriguez:

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,

Sharon M. Andrews -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181124

Device Name
Acessa ProVu System

Indications for Use *(Describe)*
The Acessa ProVu System is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.

The Acessa ProVu System includes optional electromagnetic guidance for enhancing the ultrasonic image of the Acessa ProVu Handpiece and for predicting its future path on a computer monitor screen which also shows the ultrasound B-scan image.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Acessa ProVu System is provided below.

	Primary	Secondary
Submitter's Name:	Acessa Health Inc.	Acessa Health Inc.
Submitter's Address:	7004 Bee Cave Rd, Bldg. 3, Suite 200, Austin, TX 78746	7004 Bee Cave Rd, Bldg. 3, Suite 200, Austin, TX 78746
Submitter's Telephone:	(877) 412-3828	(877) 412-3828
Submitter's Fax:	(925) 605-0327	(925) 605-0327
Contact Name:	Kim Rodriguez	Brian J. Bergeron
Date Summary was Prepared:	September 27, 2018	
Trade or Proprietary Name:	Acessa ProVu System	
Common or Usual Name:	Radiofrequency Ablation System	
Primary Product Code:	HFG (coagulator, laparoscopic, unipolar (and accessories))	
Regulation Name and Number:	Class II per 21 CFR 884.4160: Unipolar Endoscopic Coagulator-Cutter and Accessories	
Secondary Product Codes:	OEW, IYO, ITX	
Classification Panel:	Obstetrics and Gynecology	
Legally Marketed (Unmodified) Devices to Which Substantial Equivalence is Claimed:	Primary Predicate: K132744 Acessa Guidance System Secondary Predicates: K121858 The Acessa System K163121 Telemed SmartUS Ultrasound System The predicate devices have not been subject to a design related recall.	

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Acessa ProVu System provides radiofrequency (RF) ablation, ultrasound visualization and guidance within a single console and includes additional accessories. The Acessa ProVu System consists of a console with push buttons to control menu functionality. The console contains the following hardware and electronic components:

1. RF Ablation System
2. Ultrasound Visualization System
3. Guidance System

The following accessories connect to the console:

- Dual Foot pedal (one for RF ablation and one for coagulation)
- Video Cable
- Power Cord
- Acessa Pads and Acessa Pad Cable
- Acessa ProVu Handpiece and Acessa ProVu Handpiece Cable
- Acessa Transducer, either:
  - Acessa ProVu Transducer used with Acessa ProVu Transducer Sleeve (embedded with sensor), or
  - Acessa ProVu Transducer with (embedded) sensor
- Acessa Table Top Field Generator or Acessa ProVu Planar Field Generator
- Monitor (hospital-owned accessory monitor, not provided by Acessa)

The Acessa ProVu System is designed to deliver up to 200 W of RF power at 460 kHz in three operational modes: Temperature Control, Power Control and Coagulation Mode. The graphical user interface (GUI) is displayed on a hospital-owned monitor. The system enables selection of operational parameters such as the mode of operation, the ablation time, the target temperature, and the power delivery level. With the Acessa ProVu Handpiece placed in the tissue to be ablated and its electrodes deployed, RF power can be turned on. The system parameters are continuously monitored and displayed on the monitor. If the measured parameters are outside the acceptable limits, the RF energy delivery automatically stops and a message appears on the graphical user interface. RF energy during an ablation or coagulation can also be stopped at any time by the user by pressing the foot pedal.

The Acessa ProVu System uses electromagnetic tracking technology to track the positions of the Acessa ProVu Transducer used with Acessa ProVu Transducer Sleeve (or the Acessa ProVu Transducer with embedded sensor) and the Acessa ProVu Handpiece shaft and draws virtual representations of them in their spatial relationship, so that a physician can predict the Acessa ProVu Handpiece shaft's future path in relation to the features in the ultrasound slice. The use of the guidance functionality is considered an optional accessory to procedures where ultrasound is currently used for visualization, such as the Acessa System procedure.

INTENDED USE/INDICATIONS FOR USE

The Acessa ProVu System is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.

The Acessa ProVu System includes optional electromagnetic guidance for enhancing the ultrasonic image of the Acessa ProVu Handpiece and for predicting its future path on a computer monitor screen which also shows the ultrasound B-scan image.

The subject and predicate device have the same intended use.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Acessa ProVu System (K181124)	**Acessa Guidance System** (K132744)	**The Acessa System** (K121858)	**SmartUS EXT-1M/3M** (K163121)
General Information				
Classification Regulation	21 CRF §884.4160	21 CRF §884.4160	21 CRF §884.4160	21 CRF §892.1550
Classification Name	Unipolar endoscopic coagulator cutter and accessories	Unipolar endoscopic coagulator cutter and accessories	Unipolar endoscopic coagulator cutter and accessories	Ultrasonic pulsed doppler imaging system
Product Code	HFG - coagulator, laparoscopic, unipolar (and accessories)	HFG - coagulator, laparoscopic, unipolar (and accessories)	HFG - coagulator, laparoscopic, unipolar (and accessories)	IYN
Secondary Product Codes	OEW, IYO, ITX	OEW**,** IYO	N/A	ITX, IYO
Product Class	II	II	II	II
Intended Users	Health Care Professional	Health Care Professionals	Health Care Professionals	Health Care Professionals
Classification Panel	Obstetrics and Gynecology	Obstetrics and Gynecology	Obstetrics and Gynecology	Radiology
System Accessories	Field Generator Ultrasound Transducer RF Handpiece Dual foot pedal Single use pads Handpiece Cable Pad Cable Power Cord	Field Generator Ultrasound Transducer RF Handpiece Dual foot pedal Single use pads Handpiece Cable Pad Cable Power Cord	Field Generator Ultrasound Transducer RF Handpiece Dual foot pedal Single use pads Handpiece Cable Pad Cable Power Cord	
RF Functionality				
Operating Principle	Monopolar	Monopolar	Monopolar	
Max Power Delivery	200 W into 50-80 Ω	200 W into 50-80 Ω	200 W into 50-80 Ω	
Frequency	460 kHz	460 kHz	460 kHz	
Wave Form	Sinusoidal	Sinusoidal	Sinusoidal	
Temperature Display Range	15 - 125°C	15 - 125°C	15 - 125°C	
Impedance Range	0-511Ohms	0-511 Ohms	0-511 Ohms	
Duration Range	0.1 to 12 minutes	0.1 to 12 minutes	0.1 to 12 minutes	
Temperature Display	Handpiece and Pad thermocouples	Handpiece and Pad thermocouples	Handpiece and Pad thermocouples	

	Acessa ProVu System (K181124)	**Acessa Guidance System** (K132744)	**The Acessa System** (K121858)	**SmartUS EXT-1M/3M** (K163121)
Set Power Display	Yes, coagulation only	Yes, coagulation only	Yes, coagulation only	
Duration of Energy Delivery Displayed	Yes	Yes	Yes	
Control Modes	Temperature, Manual, Coagulation	Temperature, Manual, Coagulation	Temperature, Manual, Coagulation	
Power Level Controls	Yes, coagulation only	Yes, coagulation only	Yes, coagulation only	
Ablation Duration Controls	Yes	Yes	Yes	
Maximum Ablation Duration	12 minutes at target time	12 minutes at target time	12 minutes at target time	
Power Supply (PS)	100-240 V, 50/60 Hz switchable PS	100-240 V, 50/60 Hz switchable PS	100-240 V, 50/60 Hz switchable PS	
Peak Voltage	230 V	230 V	230 V	
Manual Mode Power Limit	15 W	10-15 W	10-15 W	
Number of Serial Communication Ports	Single USB port	Single USB Port	Single USB Port	
Pump used with Generator	None	None	None	
Display	Hospital-provided Monitor	LCD/Touch Screen	LCD/Touch Screen	
User Control Interface	System settings controlled at the Console.	System settings controlled with the handpiece buttons and at the RF Generator LCD/Touch Screen.	System settings controlled with the handpiece buttons and at the RF Generator LCD/Touch Screen.	
Guidance Functionality				
Tracking Technology	Electromagnetic	Electromagnetic		
Accuracy	±10 mm	±10 mm		
Views	Provide a geometrically accurate "3D" representation of the Transducer and Handpiece. Display a 2D inset view of the ultrasound video, with the added feature of the target zone overlaid on it and the laparoscopic ultrasound transducer	Provide a geometrically accurate "3D" representation of the Transducer and Handpiece. Display a 2D inset view of the ultrasound video and the laparoscopic ultrasound transducer		
Tracking System	NDI V3	NDI V2		
Ultrasound Functionality				
Ultrasound System	Ultrasound beam formers and drivers	Ultrasound beam formers and drivers (Off the shelf Aloka 6 Ultrasound system K093488)	Ultrasound beam formers and drivers (Off the shelf Aloka 6 Ultrasound system K093488)	Ultrasound beam formers and drivers
Ultrasound Transducer	Acessa ProVu Transducer (Model Number: 7500 or 7700)	Aloka UST 5526L-75 Transducer (K040719)	Aloka UST 5526L-75 Transducer (K040719)	Aloka UST 5526L-75 Transducer (K040719)

The subject device is a combination system of the previously cleared devices that includes an RF ablation system (K121858), guidance control (K132744) and an OEM ultrasound component (K163121). As evidenced by the table above, there are differences in technological characteristics between the subject and predicate device. These differences do not raise different questions of safety and effectiveness.

SUMMARY OF PERFORMANCE DATA

To further support a determination of substantial equivalence, non-clinical bench testing was conducted to support the subject device. The specific types of non-clinical testing conducted are listed below.

- Biocompatibility Testing
- Use Life Testing of Transducers
- Electrical Safety and Electromagnetic Compatibility testing per:
  - ANSI/AAMI/ES 60601-1:2005 + A2:2010 + A1:2012
  - IEC 60601-2-2: 2017
  - IEC 60601-1-2: 2014
  - IEC 60601-2-37: 2015
- Software Validation and Verification Testing per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.
- Acessa ProVu Console and Guidance System Level Testing
- Benchtop Ablation Testing to validate that the ablations created by the subject device are substantially equivalent to the predicate.
- Acessa ProVu Handpiece Performance Testing to qualify and quantify the mechanical and functional properties of the Handpiece.
- Acessa Pads Performance Testing to qualify and quantify the mechanical and functional properties of the Pads.
- Acessa ProVu Transducer Performance Testing, including Acoustical and Thermal Measurement, in conformance with IEC 60601-2-37
- Acessa ProVu Transducer Sleeve Testing to qualify and quantify the mechanical and functional properties of the Transducer Sleeve.

CONCLUSION

The performance data demonstrate that the subject device is substantially equivalent to the predicate devices.