June 21, 2019

Aqua Medical, Inc.
% Bosmat Friedman
Regulatory Affairs Consultant
ProMedoss, Inc.
3521 Hatwynn Road
Charlotte, NC 28269

Re: K183595
Trade/Device Name: Aqua Medical RF Vapor System
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KNS, GEI
Dated: May 17, 2019
Received: May 20, 2019

Dear Bosmat Friedman:

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/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 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 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,

Shanil P. Haugen, Ph.D.
Acting Assistant Division Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K183595

Device Name
Aqua Medical RF Vapor System

Indications for Use *(Describe)*
The Aqua Medical RF Vapor System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus.
Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, Angiodysplasia, Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis (RP).
The device is to be used in adults only.

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

[as required by section 807.92(c)]

Aqua Medical RF Vapor System

510(k) Number K183595

1. SUBMITTER

Applicant's Name:
Aqua Medical, Inc.
191 West Second St.
Santa Ana, CA 92701
Phone: 949-233-5172

Contact Person:
Bosmat Friedman
Regulatory Affairs Consultant
3521 Hatwynn Rd.
Charlotte, NC 28269
Phone: 647-975-3974
bosmat.f@promedoss.com

Date Prepared:
June 20, 2019

2. DEVICE

Trade Name:
Aqua Medical RF Vapor System

Classification Name: Endoscopic electrosurgical unit and accessories
Product Code: KNS
Regulation No: 876.4300
Class: 2
Review Panel: Gastroenterology/Urology

Classification Name: Electrosurgical cutting and coagulation device and accessories
Product Code: GEI
Regulation No: 878.4400
Class: 2
Review Panel: General & Plastic Surgery

3. PREDICATE DEVICE

Primary predicate:

- Halo^{90} System by Barrx Medical, Inc., cleared under K060169 and K093008

4. DEVICE DESCRIPTION

The Aqua RF Vapor System uses a catheter to deliver heat to the tissue surface undergoing treatment. The heat, which is created by the application of RF energy

to a bipolar electrode pair located inside the catheter tip, is delivered to the tissue through heated water vapor generated inside the catheter. Application of heat to the tissue results in coagulation of the tissues being treated. This technique avoids the need for direct RF energy application to heat the tissue.
The Aqua Medical RF Vapor System consists of the following components:

- **Aqua RF Vapor Generator:** A software-controlled RF generator is operated through a graphical user interface (GUI) and incorporates a syringe pump that delivers saline to the catheter. Delivery of bipolar RF energy to the catheter is controlled either by an accessory foot pedal or a button incorporated in the disposable catheter.
- **Aqua RF Vapor Catheter:** a disposable, sterile, single-use catheter with a diameter of 7 F (2.3 mm) and a length of 145 cm. It includes an integrated cable for attachment to the generator and a Luer-connector that facilitates connection to the saline delivery tubing.
- **Saline Delivery Tubing and Syringe:** Tubing and syringe (60cc) that provide a means of delivering saline to the catheter during treatment.

Mode of Operation

Access to the target tissue is gained using standard endoscopic techniques. An endoscope with the FDA cleared Olympus endoscope distal attachment cap is advanced to the treatment location. The treatment catheter is inserted through the working channel of the endoscope with a minimum of a 2.8 mm working channel, and advanced to the distal end of the endoscope until the distal tip is completely visible. The endoscope and catheter are advanced to the treatment site and the target tissue is engaged with the endoscopic cap. Bipolar RF energy is then delivered to the bipolar electrode pair in the catheter, while saline is flowing through the catheter lumen and generates heated water vapor to treat the targeted tissue.
The user chooses the power via the generator's touch-screen interface. The generator creates heated water vapor by delivering a constant bipolar RF output to the bipolar electrode contained within the lumen of the disposable catheter. The software commands the integrated syringe pump to dispense saline at a flow rate proportional to the user selected power setting. Heated water vapor, generated as saline flows over the energized electrode, is delivered to the tissue through the distal tip of the catheter. The time of application of heated water vapor determines the depth of treatment.

5. INDICATIONS FOR USE

The Aqua Medical RF Vapor System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus.
Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, Angiodysplasia, Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis (RP). The device is to be used in adults only

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the Aqua System and the HALO^{90} predicate are comprised of a multiple use generator with optional footswitch and disposables. However, the Aqua System achieves its intended use by utilizing a slightly different technology from its primary predicate. While the HALO^{90} is used to treat the esophagus by applying bipolar RF energy (creating heat) directly to the tissue, the Aqua System converts the bipolar RF energy to heated vapor which is then used to treat the tissue.
To bridge the technological gap between the two devices, comparative bench and animal testing were conducted. The results of the comparative testing demonstrate that the HALO^{90} and the Aqua Medical RF Vapor System produce substantially equivalent results.

7. PERFORMANCE DATA

Below is a list of the tests that have been performed and successfully completed for the Aqua Medical RF Vapor System.

Biocompatibility:
The following biocompatibility tests were conducted:

- Cytotoxicity
- Hemolysis
- Systemic Toxicity
- Intracutaneous
- Sensitization
- Pyrogenicity

Electrical safety and electromagnetic compatibility (EMC):
The system was tested and found to comply with IEC 60601-1:2005/EN 60601-1:2006 Medical electrical equipment -Part 1: General requirements for basic safety and essential performance 3rd Ed. and IEC 60601-1-2:2007 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests.

Software Verification and Validation Testing:
Software verification and validation testing were conducted, and documentation was provided as recommended by 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 is considered as a "major" level of concern.

Bench:

- HW Verification Testing
- System Validation Testing
- Distal Assembly Pull Test
- Lesion Comparative testing

Animal:

In order to demonstrate substantial equivalence and bridge the technological gap between the Aqua Medical RF Vapor System and its primary predicate, the company conducted an animal study including both acute and subacute animals.

A total of six animals were utilized in the study; three animals were treated and evaluated acutely (Day = 0) and three animals were treated and evaluated sub-acutely (48 hours). Each animal's esophagus received multiple test and control treatments that were applied using two different treatment settings. The histopathological evaluation assessed acute thermal coagulation through the cross-sectional layers of the esophagus. There were no pathological complications associated with the test or control treatments in any animal. Both the test and control treatments demonstrated the ability to create thermal coagulative tissue injury that penetrates in depth to the external muscularis of the esophagus in healthy swine. Neither test nor control treatments were associated with esophageal perforation, significant hemorrhage or significant clinical complication. The results of the study demonstrate that the Aqua Medical RF Vapor System and the HALO^{90} are substantially equivalent.

Conclusion:

The Aqua Medical RF Vapor System has the same indications for use as the HALO^{90} System and is substantially equivalent in technological and performance characteristics to the HALO^{90} predicate. The results obtained from comparative testing further support our substantial equivalency claim.

Consequently, it is clear that the Aqua Medical RF Vapor System is as safe and effective as its predicate devices without raising any new safety and/or effectiveness concerns. Any differences have been addressed by extensive testing and validations and therefore negate any safety or effectiveness concerns.