May 27, 2021

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

Re: K211282
Trade/Device Name: Aqua Medical RF Vapor System
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS, GEI
Dated: April 22, 2021
Received: April 27, 2021

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.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211282

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.

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510(K) SUMMARY [SPECIAL 510(K)]
Aqua Medical RF Vapor System
510(k) Number K211282

1. SUBMITTER

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

Primary Contact:
Bosmat Friedman
Regulatory Affairs Consultant
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Phone: 647-975-3974
bosmat.f@promedoss.com

Date Prepared:
April 22, 2021

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 DEVICES

Aqua Medical RF Vapor System, by Aqua Medical Inc., Product code KNS, GEI cleared Under: K183595.

4. DEVICE DESCRIPTION

The Aqua RF Vapor System uses a catheter to deliver heated water vapor to the tissue surface undergoing treatment. The Aqua RF Vapor System is a catheter-based system for heating and coagulating tissue. The heat is delivered to the target tissue in the form of water vapor that is generated within the catheter tip using RF (radiofrequency) energy. 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 Catheters**: disposable, sterile, single-use catheters with a diameter of 7 F (2.3 mm) and a length of 145 cm. There are 3 types of RF Vapor catheters available.
- **Saline Delivery Tubing and Syringe**: Tubing and syringe (60cc) provide a means of delivering saline to the catheter during 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. SUBSTANTIAL EQUIVALENCE

The Aqua RF Vapor System is substantially equivalent to the predicate device based on the following:

Intended Use
The intended use of the proposed device is identical to that of the cleared device.

Technology
The proposed device modifications introduce two new catheter designs, the Front Delivery Catheter and the Side Delivery Catheter. Both catheters have been tested to ensure they perform as intended via hardware verification testing. Furthermore, comparative simulated use bench model testing was conducted to support our substantial equivalency claim and to demonstrate that the new designs function in an equivalent manner as the previously cleared Aqua Medical RF Vapor Catheter.

Discussion

The Aqua RF Vapor System has identical indications for use as the previously cleared Aqua RF Vapor System. The main technological difference between the Aqua RF Vapor System and the predicates is the addition of two Focal Catheters that can be used with the previously cleared generator. The additional catheters have improved flexibility, eliminate the need to use a Distal Attachment Cap, have a smaller and more light-weight handle and power cable and provide the physician with more treatment options (with respect to the size and shape of the treatment area). Comparative validation testing and verification testing demonstrate that the additional catheter designs are substantially equivalent to the previously cleared Aqua RF Vapor Catheter. Consequently, the Aqua RF Vapor System is as safe and effective as its predicate without raising any new safety and/or effectiveness concerns.

7. PERFORMANCE DATA

In order to support the proposed modifications, the following tests were conducted:

- Hardware Verification Testing
- Simulated tissue model
- Biocompatibility Testing (cytotoxicity, sensitization and irritation), and
- Sterilization Validation

8. CONCLUSION

Aqua Medical has demonstrated that the Aqua RF Vapor System is substantially equivalent to the predicate device. Differences between the proposed Aqua RF Vapor System and the predicate device do not raise new questions of safety or effectiveness.