August 8, 2025

Aqua Medical, Inc.
% Bosmat Friedman-Cox
Regulatory Consultant
ProMedoss, Inc.
6026 Beech Cove Ln.
Charlotte, North Carolina 28269

Re: K251226
Trade/Device Name: Aqua Medical RF Vapor Ablation System
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS, GEI
Dated: July 11, 2025
Received: July 11, 2025

Dear Bosmat Friedman-Cox:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ANTHONY LEE -S

Anthony Lee, PhD, MBA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251226

Please provide the device trade name(s).

Aqua Medical RF Vapor Ablation System

Please provide your Indications for Use below.

The Aqua Medical RF Vapor System is indicated for use in the coagulation and ablation 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

AQUA MEDICAL	Aqua Medical RF Vapor Ablation System	
	Traditional 510(k);	510(k) Summary

1. SUBMITTER

Applicant's Name:
Aqua Medical, Inc.
6634 Owens Drive
Pleasanton, CA 94588
Phone: 949-233-5172

Primary Contact:
Bosmat Friedman
Regulatory Affairs Consultant
6026 Beech Cove Ln.
Charlotte, NC 28269
Phone: 980-308-1636
bosmat.f@promedoss.com

Date Prepared:
July 11, 2025

2. DEVICE

Trade Name:
Aqua Medical RF Vapor Ablation 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

Primary Predicate:
Aqua Medical RF Vapor System, by Aqua Medical Inc., Product code KNS, GEI cleared Under: K213627, K211282, K183595 and K241271.

4. DEVICE DESCRIPTION

The Aqua RF Vapor Ablation System is a catheter-based device that uses radiofrequency (RF) energy to produce heated water vapor for the coagulating and ablating tissue. The RF energy

heats liquid as it flows through the catheter, creating steam that is directed to the target tissue. The system includes 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. The catheter connects, fluidically and electrically, to the generator. A foot pedal is used to control the RF energy and vapor delivery.
- **Aqua RF Vapor Catheters**: disposable, sterile, single-use catheters with a diameter of 7F (2.3 mm) with an outer catheter sheath that is 10.5F and a length between 145 cm and 210 cm. Catheters are designed to be used through an endoscope working channel diameter of 3.7mm. This submission included only the modified circumferential catheter.
- **Cassette (Syringe and Tubing)**: 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 and ablation 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 reason for this submission includes modifications to the generator, modifications to the Cassette (syringe and tubing), and design modifications to the circumferential catheter. To support the requested modifications the company submitted supporting non-clinical data. The proposed modifications do not introduce new safety and effectiveness concerns and support the company's substantial equivalency claim.

7. PERFORMANCE DATA

In order to support the proposed modifications to the generator, catheter and Cassette the company conducted the following:

Generator:
- EMC & Electrical Safety
- Software validation
- Generator Hardware Verification

Catheter:
- Hardware Verification Testing
- Simulated-use tissue validation (Lean Beef Testing)

Cassette:
- Biocompatibility

- Shelf-Life assessment
- Sterilization Validation

8. CONCLUSION

Aqua Medical has demonstrated that the Aqua RF Vapor Ablation System is substantially equivalent to the predicate device. Differences between the proposed Aqua RF Vapor Ablation System and the predicate device do not raise new questions of safety or effectiveness. The requested modifications have been adequately supported with bench testing and scientific rationales.