January 22, 2019

Advanced Medical Design Co., Ltd
Silvia Yeh
Regulatory Affairs
4-5F, No 29, Wuquan 5th Rd., Wugu Dist.
New Taipei City, 24888
Taiwan

Re: K181887
Trade/Device Name: AMD Anti-Fog Solution
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OCT
Dated: July 10, 2018
Received: December 12, 2018

Dear Silvia Yeh:

We reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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,

Mark R. Kreitz -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)*
K181887

Device Name
AMD Anti-Fog Solution

Indications for Use *(Describe)*
AMD Anti-Fog Solution is a sterile and single-use laparoscopic accessory device for use prior to and during endoscopic and laparoscopic procedures. The product is intended to prevent condensation of the distal lenses of the endoscopic/ laparoscopic instruments during the surgery. The product is intended for prescription use 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

I. SUBMITTER

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Date Prepared: July 10, 2018

II. DEVICE INFORMATION

Name of Device: AMD Anti-Fog Solution
Common or Usual Name: Endoscope Anti-fogging Device
Classification Name: Endoscope and accessories (21 CFR 876.1500)
Regulatory Class: II
Product Code: OCT

III. PREDICATE DEVICE

Trade/Device Name	Clear-It Anti-Fog Solution
Common or Usual Name	Endoscope Anti-fogging Device
510(k) Number	K022826
Product Code	OCT
Submitter	Preservation Solution, Inc.

IV. DEVICE DESCRIPTION

The AMD Anti-Fog Solution is a single-use, sterile, and biocompatible laparoscopic accessory device. The product is packaged by the Tyvek® Pouch which includes one clear plastic screw top dispenser bottle with the volume of 6 mL and one polyurethane (PU) foam pad with x-ray detectable radiopaque

ribbon. The solution is a clear/colorless, odorless, and aqueous solution which comprises of surfactant (≦2%), isopropyl alcohol (≦2%), and water (≧96%). The polyurethane (PU) foam pad is an adhesive-backed sponge with radiopaque ribbon that can be used to introduce the solution into the surface of the lenses.

The device is intended to be used prior and during minimally invasive surgical operation, to prevent condensation of the distal lenses of the endoscopic/laparoscopic instruments during the clinical operation. AMD Anti-Fog Solution is comprised of a surfactant that provides the same physical characteristics as the predicate device. The mechanism of anti-fogging function of AMD Anti-Fog Solution is to reduce the surface tension of the water, resulting in a non-scattering film of water instead of single droplets, on the lenses once the product is smeared on the lenses. Therefore, the non-scattering film of water was formed on the lenses instead of the single water droplets. This phenomenon is called “wetting”.

V. INDICATIONS FOR USE

AMD Anti-Fog Solution is a sterile and single-use laparoscopic accessory device for use prior to and during endoscopic and laparoscopic procedures. The product is intended to prevent condensation of the distal lenses of the endoscopic/laparoscopic instruments during the surgery. The product is intended for prescription use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

AMD Anti-Fog Solution is designed to prevent condensation of the distal lenses, that is the same as the predicate device (K number: K022826). A comparison of the device features, technological characteristics, intended use, and other information demonstrates that AMD Anti-Fog Solution is substantially equivalent to the predicate device. The substantially equivalent comparison table was summarized in Table 5.1.

Table 5.1. The Substantially Equivalent Comparison Table

Device Name	Proposed Device	Predicate Device	Comment
	AMD Anti-Fog Solution	Clear-It Anti-Fog Solution (K022826)	
Indication for Use	AMD Anti-Fog Solution is a sterile and single-use laparoscopic accessory device for use prior to and during endoscopic and laparoscopic procedures. The product is intended to prevent condensation of the distal lenses of the endoscopic/laparoscopic instruments during the surgery. The product is intended for prescription use only.	Clear-It Anti-Fog Solution is indicated for use in the sterile surgical arena to eliminate condensation from endoscopic lenses, goggles and other devices that are likely to fog.	Same
Reusable / Disposable	Disposable	Disposable	Same
Target Patient Population	The patient who treated by minimum invasive laparoscopic surgery.	The patient who treated the surgery in the sterile surgical arena.	Similar. The patient population of the proposed device is for minimum invasive laparoscopic surgery, the predicate device included.
Target User Population	Prescription use only	Prescription use only	Same
Where Used	Hospital O.R. room	Hospital O.R. room	Same
Contraindications	There are no known contraindications to the patient.	N/A	Same
Comprised	a. Solution	a. Solution	Similar. The

Table 5.1. The Substantially Equivalent Comparison Table

Device Name	Proposed Device	Predicate Device	Comment
	AMD Anti-Fog Solution	Clear-It Anti-Fog Solution (K022826)	
Elements	- Surfactant (≦2%) - Isopropyl alcohol (≦2%) - Water (≧96%) b. Sponge - Polyurethane (PU) foam	- Water - Isopropyl alcohol - Sodium Alcohol Ether Sulfate - Ammonium Dodecylbenzene b. Sponge - Polyurethane (PU) foam	biological evaluation results of the proposed device meet the requirements of the applicable standards.
Method of Introduction	Wiping distal end of the lens by sponge with solution.	Wiping distal end of the lens by sponge with solution.	Same
Compatibility With Other Devices	Laparoscope/Endoscope: 5 mm, 10 mm and all other sizes	Laparoscope/Endoscope: 5 mm, 10 mm and all other sizes	Same
Performance	Preventing condensation of the distal lenses of the endoscopic/laparoscopic instruments during the clinical operation.	Preventing condensation of the distal lenses of the endoscopic/laparoscopic instruments during the clinical operation.	Same
Safety	The following biocompatibility tests were conducted. - Cytotoxicity Test - Sensitization Test - Intracutaneous Reactivity Test - Acute Systemic Toxicity Test - Material-Mediated Pyrogenicity Test All of the tests passed the requirements as indicated in the applicable standards.	The cytotoxicity test was conducted.	Same. We performed all of the biocompatibility tests that are indicated in the FDA recognized standards.

Table 5.1. The Substantially Equivalent Comparison Table

Device Name	Proposed Device	Predicate Device	Comment
	AMD Anti-Fog Solution	Clear-It Anti-Fog Solution (K022826)	
Sterile Barrier	Single Layer Of Tyvek® Pouch	Single Layer Of Tyvek® Pouch	Same
Sterilization Method	Gamma-radiation Sterilization (10^{-6} SAL)	Gamma-radiation Sterilization (10^{-6} SAL)	Same
Energy Source	No energy source	No energy source	Same

Through the substantially equivalent comparison table, the differences do not raise any different issues on the safety or effectiveness of the product.

VII. PERFORMANCE DATA

A series of the studies were performed to evaluate the safety and effectiveness of AMD Anti-Fog Solution. The following test results were provided to confirm the product is safe and effective as indicated.

A. Biocompatibility Testing

The biocompatibility test was evaluated per the FDA recognized consensus standard named “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016, the biocompatibility tests include the following items since the product is classified as the classification.

Nature of Body Contact		Contact Duration
Category	Contact	
External communicating device	Tissue/bone/dentin	Limited (≦24 h)

No.	Test Name	Applicable Standards	Comment
1	Cytotoxicity Test	ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For *In Vitro* Cytotoxicity	Pass
2	Sensitization Test	ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	Pass
3	Intracutaneous	ISO 10993-10:2010 Biological Evaluation Of Medical	Pass

No.	Test Name	Applicable Standards	Comment
	Reactivity Test	Devices - Part 10: Tests For Irritation And Skin Sensitization	
4	Acute Systemic Toxicity Test	ISO 10993-11:2017 Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity	Pass
5	Material-Mediated Pyrogenicity	USP <151> Pyrogen Test	Pass

All of the test studies listed above showed that AMD Anti-Fog Solution did not raise any safety issues and is biocompatible.

B. Sterilization Validation and Shelf Life Study

The product is designed to perform gamma-radiation sterilization prior to place into the market, therefore the following studies should be evaluated by the applicable standards/guidance.

a. Gamma-radiation Sterilization Validation Study

The gamma-radiation sterilization validation study was performed per the requirements of the FDA recognized consensus standards listed below.

- ISO 11137-2:2013 Sterilization of Health Care Products - Radiation - Part 2: Establishing the Sterilization Dose
- ISO 11737-1:2006 Sterilization of Medical Devices - Microbiological Methods - Part 1: Determination of A Population of Microorganisms on Products
- ISO 11737-2:2009 Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility Performed in The Definition, Validation And Maintenance Of A Sterilization Process

The method used for gamma-radiation sterilization validation study was VDmax 25 method, since the product bioburden was less than 1000 CFU/sample. The test reports showed that the product can become sterile when the routine sterilization parameter was controlled at the dose of no less than 25 kGy, which meets the regulatory requirement of sterile condition (SAL < 10^{-6}).

b. Product Aging Validation Study (Shelf Life Study)

The product aging validation study was performed for 5 years per the FDA recognized consensus standards “ISO 11607-1:2006 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems And Packaging Systems” to determine the shelf life of the product, since the product is supplied in the sterile status.

The Aging Validation Study included the following test studies.

Since the shelf life of the product is proposed to be stored for 5 years, the aging validation study is

performed which included the following test items.

No.	Test Item	Applicable Standards/Guidance	Comment
1	Package Integrity Test (Dye penetration Test)	ASTM F1929-15 Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration	Pass
2	Seal Peel Strength Test	ASTM F88/F88M-15 Standard Test Method For Seal Strength Of Flexible Barrier Materials	Pass
3	Product Sterility Test	ISO 11737-2:2009 Sterilization Of Medical Devices - Microbiological Methods - Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process	Pass
4	Product Stability Studies (Fog Resistance Test)	N/A (followed by the internal testing protocol)	Pass

All of the aging test data showed that the product can be safe and effective during its predetermined shelf life. Hence, the sterile assurance level and the functional specification of the product meet the firm's definition and regulatory requirement, the shelf life of the product is 5 years.

C. Product Performance Test

The test result of the fog resistance test shows that AMD Anti-Fog Solution is as effective as the predicate device.

VIII. CONCLUSIONS

Based on the previous data and comparison to the predicate device, AMD Anti-Fog Solution is as safe and effective as the predicate device and do not raise any new issues of safety and effectiveness.