February 26, 2024

Batrik Medical Manufacturing Inc.
Suzy Bairos
President
2165 46th Ave
Lachine, Quebec H8T 2P1
Canada

Re: K231822
Trade/Device Name: GOLFF Sterile Anti-Fog Solution
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCT
Dated: January 25, 2024
Received: January 25, 2024

Dear Suzy Bairos:

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.

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,

Shanil P. Haugen -S

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)*
K231822

Device Name
GOLFF Sterile Anti-Fog Solution

Indications for Use *(Describe)*
The GOLFF Sterile Anti-Fog Solution is a single-use, medical device, anti-fog solution used by hospital staff to apply on lenses of endoscopic and laparoscopic cameras. The solution is provided in an easy-to-squeeze bottle and comes with an adhesive-backed sponge for secure placement.

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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SECTION 5.0-510 (k) Summary

Batrik Medical Manufacturing Inc. 2165 46th Ave., Lachine, Quebec, H8T 2P1, Canada
Phone: (800) 661-5432 | Website: www.surgmed.com

1. Submitter Information:

Date of 510(k) Summary: 1/24/2024
Submitter: Batrik Medical Manufacturing Inc
Preparer and Contact Name: Heli Thakkar, Regulatory and Quality Manager
Email: hthakkar@surgmed.com
510(k) Owner: Suzy Bairos, President
Email: sbairos@surgmed.com
Address: 2165 46th Ave., Lachine, Quebec, H8T 2Pl, Canada
Phone: 514-631-7988 Ext. 21 / Fax: 514-631-9083

2. Device Name and Classification:

Common Name of Device:	Anti-Fog Solution
Device Proprietary Name:	GOLFF Sterile Anti-Fog Solution
Review Panel:	Gastroenterology/Urology
Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscope and Accessories
Class:	II
Product Code:	OCT

3. Substantial Equivalence:

Legally marketed devices with equivalence are claimed:

- Primary Predicate: Aspen Surgical Inc. Dr. Fog:510(k) K932449
- Secondary Predicate: Medline Anti-Fog Solution 510(k) Kl 52948

4. Device Description:

GOLFF Sterile Anti-Fog Solution is used to prevent fogging on endoscopic/laparoscopic lenses. It ensures clearer vision and avoids unnecessary interruptions during surgery. It also comes with an adhesive-backed sponge, for secure placement, which is also radio-opaque and not made with natural rubber latex. The product is available under reference code GOLFF-Rl.

There are no additional accessories associated with the product.

Diseases/Conditions for diagnosis, treatment, prevention, cure, or mitigation: None

Prescription Use Medical Device

5. Indications for Use:

The GOLFF Sterile Anti-Fog Solution is a single-use, medical device, anti-fog solution used by hospital staff to apply on lenses of endoscopic and laparoscopic cameras. The solution is provided in an easy-to-squeeze bottle and comes with an adhesive-backed sponge for secure placement.

6. Predicate Device:

a. Primary Predicate: Aspen Surgical Inc. Dr. Fog 510(k) K932449 dated ll-AUG-1993 is similar in intended use, handling and technology compared to the device described in this submission.
b. Secondary Predicate: Medline Anti-Fog Solution 510(k) K152948 dated 04-FEB-2016 is similar in intended use,

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handling and technology compared to the device described in this submission.

c. Comparison of Technological Characteristics with the Predicate Device:

Company	**Batrik Medical Manufacturing Inc.**	Primary Predicate **Aspen Surgical Inc. (K932449)**	Secondary Predicate **Medline (K152948)**
Model	GOLFF Sterile Anti-Fog Solution	Dr. Fog	Medline Anti-Fog Solution
Classification	Class II Device, OCT	Class II Device, OCT	Class II Device, OCT
Indications for Use	The GOLFF Sterile Anti-Fog Solution is a single-use, medical device, anti-fog solution used by hospital staff to apply on lenses of endoscopic and laparoscopic cameras. The solution is provided in an easy-to- squeeze bottle and comes with an adhesive-backed sponge for secure placement.	Intended as an anti-fog agent for endoscopic camera lenses. - Removes fog formation on lens and allows the procedure to be uninterrupted.	Intended as an anti-fog agent for endoscopic camera lenses. - Removes fog formation on lens and allows the procedure to be uninterrupted.
Description	GOLFF Sterile Anti-Fog Solution by Regulation 21 CFR 876.1500 under FDA product code, OCT. GOLFF is a single use, disposable medical device provided sterile. GOLFF is offered in a sterile, sealed pouch with a bottle filled with anti-fog solution and a sponge with an adhesive backing lined with a barium strip.	Sterile Anti-Fog Solution by Regulation 21 CFR 876.1500 under FDA product code, OCT. A single use, disposable medical device provided sterile. Offered in a sterile sealed pouch with a bottle filled with anti-fog solution and a sponge with an adhesive backing lined with a barium strip.	Sterile Anti-Fog Solution by Regulation 21 CFR 876.1500 under FDA product code, OCT. A single use, disposable medical device provided sterile. Offered in a sterile sealed pouch with a bottle filled with anti-fog solution and a sponge with an adhesive backing lined with a barium strip.
Material	**Bottle, cap and tip:** Polyethylene **Sponge:** open cell polyester **Strip:** Barium **Solution:** deionized water, isopropyl alcohol, surfactant	**Bottle, cap and tip:** Polyethylene **Sponge:** open cell polyester **Strip:** Barium **Solution:** surfactant, isopropyl alcohol, water	Unknown
Safety	The following biocompatibility tests were conducted. - Cytotoxicity Test - Sensitization Test - Intracutaneous Reactivity Test All of the tests passed the requirements as indicated in the applicable standards	Unknown: All of the biocompatibility tests that are indicated in the FDA recognized standards were performed.	Unknown: All of the biocompatibility tests that are indicated in the FDA recognized standards were performed.
Sterility	Sterile	Sterile	Sterile
Use	Single Use, Disposable	Single Use, Disposable	Single Use, Disposable
Where is it used	Hospital O.R. Room	Hospital O.R. Room	Hospital O.R. Room
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation

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i. **Performance Data**

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

1. Product Functional Testing

Benchtop Test	**Batrik Medical Manufacturing Inc.** GOLFF Sterile Anti-Fog Solution
Deformation/Degradation	Pass
Easy Removal of Release Liner	Pass
Adhesive Backing Functional	Pass
Squeeze Test	Pass
Transparency of Bottle	Pass
Bottle Shape	Pass
Anti-Fog Functional Test	Pass

ii. **Biocompatibility testing**

Test	**Batrik Medical Manufacturing Inc.** GOLFF Sterile Anti-Fog Solution
Cytotoxicity Test ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	Pass: Non-Cytotoxic
Sensitization Test ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	Pass: Non-Sensitizing
Intracutaneous Reactivity Test: ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	Pass: Non-Irritating

All tests mentioned above showed that GOLFF Sterile Anti-Fog Solution did not raise any safety issues and is biocompatible.

iii. **Sterilization Validation and Shelf-Life Study**

The product is designed to undergo gamma-radiation sterilization prior to place into the market. The gamma-radiation sterilization validation study was performed, and passed, 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 11737-1:2018 Sterilization of Medical Devices - Microbiological Methods - Part 1: Determination of A Population of Microorganisms on Products
- ISO 11737-2:2019 Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility Performed in The Definition, Validation, and Maintenance of a Sterilization Process

SECTION 5.0 - 510 (k) Summary

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1. Product Aging Validation Study (Accelerated aging testing)
   The product aging validation study was performed to simulate 4 years of aging.

No.	Test Name	Applicable Standards	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 11737-2:2019 Sterilization Of Medical Devices -Microbiological Methods - Part 2: Tests Of SterilityPerformed 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

iv. Conclusions

Based on the testing conducted and equivalency in performance demonstrated between the Batrik, Aspen Surgical Inc., and Medline Inc. devices, in conjunction with biocompatibility demonstrated via EN ISO 10993-5 and EN ISO 10993-10 evaluations, evidence has been submitted to demonstrate that GOLFF Sterile Anti-Fog Solution is substantially equivalent to the predicate.