May 2, 2024

Palliare Ltd.
% Paul Dryden
President
ProMedic Consulting LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K232902
Trade/Device Name: EVA15 insufflator
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: April 24, 2024
Received: April 24, 2024

Dear Paul Dryden:

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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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Date Prepared: 2-May-24

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Submission Correspondent:
Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: EVA15 Insufflator
Common/Usual Name: CO2 insufflator
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Product Code: HIF
Predicate Device: K222901 – Palliare EVA15
Reference Device: K131402 – Buffalo Filter VISICLEAR

Modifications:
We have provided an accessory, Auto-Evac, as an alternative to the pneumatic foot pedal used by the predicate – K222901 to activate and de-activate the EVA15 smoke evacuation functionality.

Device Description:
The EVA15 insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend a cavity by filling it with gas and to evacuate surgical smoke. It is indicated to facilitate the use of various endoscopic and laparoscopic instruments by filling the abdominal cavity or rectum with gas to distend it, and by evacuating surgical smoke. The EVA15 Insufflator is used in an operating room or endoscopic suite. It consists of the following major components: (1) a micro-processor-controlled insufflation and smoke evacuation unit, and (2) a disposable tube set.

The laparoscopic tube set is a sterile, single-use product. The EVA15 Insufflator is an active medical device, nonsterile and reusable and is intended to insufflate a body cavity up to 25 mmHg and with up to 40 SLPM instantaneous flow. The EVA15 is powered by AC and uses compressed 50 psi CO_2 and air gas supplies to supply the pneumatic circuitry for insufflation and smoke evacuation respectively.

Principle of Operation:
The operating principle employs 2 methods. A) A digital insufflation pressure regulation system using compressed CO_2 gas to deliver CO_2 into the patient cavity to be insufflated at the direction and control of the physician and B) The use of a venturi method to create a vacuum to evacuate any smoke created during the procedure. Smoke evacuation in the predicate is activated/deactivated by sequentially pressing a pneumatic foot-pedal. AutoEvac comprises a battery-operated pneumatic pump along with an antenna to detect when an electrical energy system has been activated. Using the same pneumatic connection as used in the predicate, when energy is activated the pump turns on, causing the smoke evacuator to switch on, and when energy is de-activated the pump turns off up to 5 seconds later which turns off the smoke evacuator.

Indications for Use:
The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, rectum, colon, esophagus, stomach or thoracic cavity with up to 25 mmHg pressure, by filling it with gas and to evacuate surgical smoke.

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Patient Population:
Patients undergoing laparoscopic or endoscopic procedures in which insufflation may be helpful.

Environments of use:
Operating room or endoscopy suite.

Table 1 is a comparison – Subject Device vs. the Predicate, K222901 – Palliare EVA15.

Substantial Equivalence Discussion
The EVA15 insufflator has the identical intended use and indications, technological characteristics, and principles of operation as the predicate Palliare EVA15, K222901. There has been no change to the EVA15 system, but an additional accessory is made available to activate/de-activate smoke evacuation.

Intended Use/ Indications for Use
Unchanged from the predicate

Technological Characteristics
The modification does not change the technological characteristics of the EVA15 insufflator and smoke evacuation system. The AutoEvac accessory provides an alternative means of turning on and off smoke evacuation. Both AutoEvac and the foot pedal accessories activate/deactivate smoke evacuation using the same pneumatic tube. The AutoEvac accessory does not employ software.

Principles of Operation
The EVA15 Insufflator principle of operation remains unchanged to the predicate.

Non-clinical Testing
Performance testing of the insufflator has demonstrated the ability to activate and de-activate smoke evacuation when electrosurgical energy is switched on and off, including testing to IEC 60601-1:2005/AMD1:2012 / AMD 2:2020 (Edition 3.2) – Medical Electrical Equipment - Part 1: General Requirements For Safety and IEC 60601-1-2:2014 / A1:2020 (Edition 4.1) – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Substantial Equivalence Conclusion
The EVA15 with the AutoEvac accessory has the same intended use, indications, technological characteristics and principles of operation as the predicate.

This difference does not raise different questions of safety or effectiveness as compared to the predicate device because smoke evacuation is activated/de-activated using the same pneumatic principle.

The AutoEvac accessory uses energy sensing to activate and de-activate smoke evacuation in a similar manner to the reference device, Buffalo Filter Visiclear – K131402, which has an accessory called the EZLink automatic activation device. The results of non-clinical performance testing demonstrate that the subject device is as safe and effective as the predicate device to support a substantial equivalence determination.

Table 1 – Comparison – Subject vs. Predicate

	Subject Device: **EVA15 Insufflator with AutoEvac**	**Predicate:** **EVA15 Insufflator -** K222901	**Comparison**
Manufacturer	Palliare	Palliare	
Classification	21 C.F.R. § 884.1730 (*Laparoscopic Insufflator*) Product Code HIF (Class II)	21 C.F.R. § 884.1730 (*Laparoscopic Insufflator*) Product Code HIF (Class II)	Same
Fundamental scientific technology	Digital insufflation pressure regulation system using compressed CO_2 gas. Venturi smoke evacuation.	Digital insufflation pressure regulation system using compressed CO_2 gas. Venturi smoke evacuation.	Same
Patient connection	Standard Trocar luer connection	Standard Trocar luer connection	Same
Indications for Use	The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, rectum, colon, esophagus, stomach or thoracic cavity with up to 25 mmHg pressure, by filling it with gas and to evacuate surgical smoke.	The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, rectum, colon, esophagus, stomach or thoracic cavity with up to 25 mmHg pressure, by filling it with gas and to evacuate surgical smoke.	Same
Gas Delivery Modes	Intermittent Pressure (Standard) Insufflation Continuous Pressure Insufflation	Intermittent Pressure (Standard) Insufflation Continuous Pressure Insufflation	Same
Smoke Evacuation	Available in all modes. Operates continuously or may be activated on/off using foot pedal or automatically using the AutoEvac accessory.	Available in all modes. Operates continuously or may be activated on/off using foot pedal.	Alternative accessory provided for automatic activation and deactivation of smoke evacuation
Technology of energy sensing	Activates which surgical energy is sensed	Not available, but use of a reference Buffalo Filter Visiclear – K131402 EZLink automatic activation device when surgical energy is sensed.	Buffalo Filter Visiclear – K131402 EZLink automatic activation device when surgical energy is sensed.

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	Subject Device: **EVA15 Insufflator**	**Predicate:** **EVA15 Insufflator -** K222901	**Comparison**
Flow Range	0-40 SLPM	0-40 SLPM	Same
Pressure Range	Up to 25 mmHg	Up to 25 mmHg	Same
Accessories	Tubeset	Tubeset	Same
Use limitation of tube set	48 hours due to ID Chip	48 hours due to ID Chip	Same
Dimensions	160x130x330mm	160x130x330mm	Same
Weight	5.5kg	5.5kg	Same
Power Source	100-240V	100-240V	Same
Tubeset Sterilization	EtO	EtO	Same
User Interface	Membrane Panel	Membrane Panel	Same
Testing	IEC 60601-1 Electrical safety IEC 60601-1-2 - - EMC	Similar	Similar

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232902

Device Name
EVA15 Insufflator

Indications for Use *(Describe)*
The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, rectum, colon, esophagus, stomach or thoracic cavity with up to 25 mmHg pressure, by filling it with gas and to evacuate surgical smoke.

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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