October 21, 2020

Palliare Ltd.
% Paul E. Dryden
Consultant
Palliare Ltd. c/o ProMedic Consulting, LLC
131 Bay Point Dr. NE
St. Petersburg, FL 33704

Re: K202799
Trade/Device Name: EVA15 Insufflator
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, FCX
Dated: September 21, 2020
Received: September 23, 2020

Dear Paul E. 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 (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,

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

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)*
K202799

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 15 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared:	21-Oct-20
Submitter:	Palliare Ltd. Galway Business Park, Dangan Galway H91 P2DK, Ireland Tel - + 353-91-516362
Official Contact:	John O'Dea, Ph.D., Director
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	EVA15 Insufflator
Common/Usual Name:	CO_2 insufflator
Regulation Number:	21 CFR 884.1730
Regulation Name:	Laparoscopic insufflator
Product Code:	HIF, FCX
Regulatory Class:	Class II
Predicate Device:	K193520 – Palliare EVA15

The predicate device has not been subject to a design-related recall.

Modification:

The indications for use for the subject device have been modified from that of the predicate to include specific reference to insufflation of the rectum, esophagus, and stomach. There are no proposed design changes in this 510(k). The subject device remains identical in design to the predicate.

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.

There are 3 operating modes:

(a) Continuous Flow (similar to a traditional endoscopic insufflator) – delivers a fixed flow between 0 and 15 standard liters per minute (SLPM)

(b) Intermittent Pressure Insufflation (similar to traditional laparoscopic insufflation) – a pressure is targeted, but the flow delivered in targeting that pressure is limited to 12 SLPM (i.e. no more than 12 SLPM will be delivered during intermittent pressure insufflation).

(c) Continuous Pressure Insufflation – a pressure is targeted, but the flow delivered in targeting that pressure is limited to 40 SLPM (i.e. no more than 40 SLPM will be delivered during continuous pressure insufflation).

510(k) Summary

The 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 15mmHg 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.

Patient Population:

Patient undergoing laparoscopic or endoscopic procedures in which insufflation may be helpful

Environment of use:

Operating room or endoscopy suite.

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 15 mmHg pressure, by filling it with gas and to evacuate surgical smoke.

A comparison of Technological Characteristics of the subject and predicate devices are presented in **Table 1** below.

K202799

510(k) Summary

Table 1 – Comparison – Subject vs. Predicate

	Predicate: **EVA15 Insufflator - K193520**	**Subject Device:** **EVA15 Insufflator**	**Comparison**
Manufacturer	Palliare	Palliare	Same
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, FCX (Class II)	Similar
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, colon or thoracic cavity with up to 15 mmHg pressure, by filling it with gas and to evacuate surgical smoke.	The EVA 15 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 15 mmHg pressure, by filling it with gas and to evacuate surgical smoke.	Similar
Gas Delivery Modes	Fixed Flow Intermittent Pressure (Standard) Insufflation Continuous Pressure Insufflation	Fixed Flow 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.	Available in all modes. Operates continuously or may be activated on/off using foot pedal.	Same
Flow Range	0-40 SLPM	0-40 SLPM	Same
Pressure Range	7-15 mmHg	7-15 mmHg	Same
Accessories	Tubeset	Tubeset	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

K202799

510(k) Summary

Discussion of Differences:

The differences in indications between the subject device and the predicate do not constitute a new intended use.

The subject and predicate device have the same technological characteristics.

Summary of Non-clinical Performance Testing:

As the subject device is identical in design to the predicate, performance data from the predicate device were leveraged to support the performance of the subject device.

Substantial Equivalence Conclusion:

The difference in indications between the subject device and the predicate do not constitute a new intended use. The subject and predicate device have the same technological characteristics. Therefore, the subject device is as safe and effective as the predicate device.