January 27, 2023

Palliare Ltd.
% Paul Dryden
President/Consultant for Strata
ProMedic Consulting, LLC
131 Bay Point Dr. NE
St. Petersburg, FL 33704

Re: K222901
Trade/Device Name: EVA15 Insufflator
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, FCX
Dated: December 20, 2022
Received: December 20, 2022

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 (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 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

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)*
K222901

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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Date Prepared: 26-Jan-23

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

Predicate Device: K202799 – Palliare EVA15
Common/Usual Name: CO_2 insufflator
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Product Code: HIF, FCX

Modification:
Updated maximum pressure delivered to 25 mmHg, the ability to select two insufflation pressures and select using the foot pedal, and a chip identifier in the tubeset connectors.

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 25mmHg 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.

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.

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, K202799 – Palliare EVA15.

Substantial Equivalence Discussion

The EVA15 insufflator has the same general intended use and indications, technological characteristics, and principles of operation as the predicate Palliare EVA 15, K202799.

Intended Use/ Indications for Use
The proposed modifications to the indications for use are to extend the pressure delivery range from 15 mmHg to 25 mmHg

Technological Characteristics
The modification does not change the technological characteristics.

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

Non-clinical Testing
Performance testing of the insufflator in the revised pressure range demonstrated that the subject device met its acceptance criteria, the same acceptance criteria as applied to the predicate. Testing included:

- Static condition
    - Pressure accuracy
- Dynamic condition
    - Simulated leak
    - Smoke evacuation

The addition of the ID Chipset to the disposable tubeset connector is to ensure that the correct tubeset is used and to limit the time the disposable tubeset may be used. Software verification and validation was performed to test that the EVA15 insufflator could read the connector chip correctly to determine the presence of the chipset and the identity of the tubeset. Verification of the spring pressure relief valve performance was performed.

Substantial Equivalence Conclusion
The EVA15 with the modified performance and addition of the ID chip in the tubeset remain to have the same intended use and similar indications, technological characteristics and principles of operation.

This difference does not present different questions of safety or effectiveness than the predicate device because CO_2 is delivered to the surgical field at a maximum 25 mmHg, which is lower than other marketed devices e.g., K153513 – World of Medicine Model FM134, and smoke is evacuated without loss of cavity pressure as with the currently cleared EVA15- K202799. The results of non-clinical performance testing demonstrate that the subject device is as safe and effective as the predicate. Thus, the EVA15 Insufflator is substantially equivalent to the Palliare EVA 15, cleared under K202799.

Table 1 – Comparison – Subject vs. Predicate

	Proposed Device: EVA15 Insufflator	**Predicate:** **EVA15 Insufflator -** K202799	**Comparison**
Manufacturer	Palliare	Palliare	
Classification	21 C.F.R. § 884.1730 (*Laparoscopic Insufflator*) Product Code HIF, FCX (Class II)	21 C.F.R. § 884.1730 (*Laparoscopic Insufflator*) Product Code HIF, FCX (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 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 25 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 except extension of pressure range
Gas Delivery Modes	Intermittent Pressure (Standard) Insufflation Continuous Pressure Insufflation	Fixed Flow Intermittent Pressure (Standard) Insufflation Continuous Pressure Insufflation	Fixed flow not offered in proposed product
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	Up to 25 mmHg	7-15 mmHg	Different but similar to the reference K153515
Accessories	Tubeset	Tubeset	Same as cleared under K193520 and K202922 except for addition of ID Chip
Use limitation of tube set	48 hours due to ID Chip	Labeling was disposable but nothing prevented continued use	Addition of ID chip

	Proposed Device: EVA15 Insufflator	**Predicate:** **EVA15 Insufflator -** K202799	**Comparison**
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