July 8, 2021

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

Re: K202922
Trade/Device Name: END 200 Tubeset
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FCX
Dated: June 6, 2021
Received: June 8, 2021

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,

for
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)*

K202922

Device Name

END-200 Tubeset

Indications for Use *(Describe)*

The END-200 Tubeset is intended to be used with the EVA15 insufflator, to supply CO_2 to an endoscope during gastrointestinal endoscopic procedures.

Type of Use *(Select one or both, as applicable)*

XX 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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510(k) Summary

Date Prepared: 7-Jul-2021

Palliare Ltd.
Galway Business Park, Dangan
Galway H91 P2DK, Ireland

Official Contact: John O'Dea, Ph.D., Director

Submission Correspondent: Paul Dryden
ProMedic, LLC

Device Name: END-200 Tubeset
Common Name: Endoscope and accessories
Regulation Number: 21CFR 876.1500
Regulation Name: Endoscope and accessories
Product Code: FCX
Regulatory Class: II
Device Panel: Gastroenterology/Urology

Predicate Device: K053008 – E-Z-EM, Inc. – E-Z-EM Endoscopic CO_2 regulator
Reference Device: K163614 – Pentax Medical - PENTAX Medical ED34-i10T, Video Duodenoscope

Device Description:
The END-200 Tubeset is a dual lumen tube with clips that attach to the outside of an endoscope. It connects to a CO_2 gas source and is used to insufflate the cavity during an endoscopic procedure, and to provide a line to monitor pressure. It is single use, disposable and provided non-sterile similar to the predicate. The ENDO-200 Tubeset is offered in Small and Medium sizes.

Principle of Operation:
The device is a simple dual lumen conduit from an insufflator to an anatomical cavity being insufflated. One lumen is used when monitoring pressure in the cavity and the other lumen is used to delivered CO_2 from the insufflator.

Indications for Use:
The END-200 Tubeset is intended to be used with the EVA15 insufflator, to supply CO_2 to an endoscope during gastrointestinal endoscopic procedures.

Patient Population:
Patients undergoing 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, K053008 and includes a discussion of the reference device, K163614.

Table 1 – Comparison – Subject vs. Predicate / Reference

	Predicate: **EZ-EM, Inc. – E-Z-EM Endoscopic CO_2 regulator** **K053008**	**Reference** **PENTAX Medical ED34-i10T, Video Duodenoscope accessory** **K163614**	**Proposed Device:** **END-200 Tubeset**	**Comparison**
Manufacturer	E-ZEM, Inc. (now Bracco Diagnostics, Inc)	Pentax Medical	Palliare	
Classification	21 C.F.R. § 876.1500 Product Code - FCX	21 C.F.R. § 876.1500 Product Code - FDT	21 C.F.R. § 876.1500 Product Code - FCX	Similar. The reference is for the external accessory reference only.
Fundamental scientific technology	Tube that connects to the endoscope and delivers CO_2 during endoscopic procedures	Detachable Distal Cap	Tube that connects to the endoscope and delivers CO_2 during endoscopic procedures	Same
Indications for Use	The CO_2 endoscopic Insufflator In-line tubing set is intended to connect a CO_2 source (insufflator), and a sterile water source (water bottle), to an endoscope to supply CO_2 during gastrointestinal endoscopic procedures.	The PENTAX Duodenoscope ED34-i10T is intended to provide optical visualization of (via a video monitor), and therapeutic access to, Biliary Tract via the Upper Gastrointestinal Tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic and Cystic Ducts. These instruments are introduced via the mouth when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.	The END-200 tubeset is intended to be used with the EVA15 insufflator, to supply CO_2 to an endoscope during gastrointestinal endoscopic procedures.	Similar except subject device is not connected to water source With regards to the reference we are only referring to the external cap which has a similar design as an external accessory to the endoscope.

Compatibility	Connects to OEM Endoscope systems that are equipped with an external luer connector	Connects to endoscope systems	Connects to OEM Endoscope systems	Same
Sterile	Non-sterile	Sterilized prior to use	Non-sterile	Same
Disposable	Single patient use, disposable	Single patient use, disposable	Single patient use, disposable	Same
Shelf-life	6 years	Not stated	1 year	Similar
Biocompatibility	ISO 10993-1 Surface Contact, mucosa, limited duration	ISO 10993-1 Surface Contact, mucosa, limited duration	ISO 10993-1 Surface Contact, mucosa, limited duration	Similar

Substantial Equivalence Discussion
The END-200 Tubeset has the same general intended use and indications, technological characteristics, and principles of operation as the predicate.

Intended Use/ Indications for Use
The proposed indications for use are similar to the predicate.

Technological Characteristics
The technology of a set of tubing with connectors that can attach to an endoscope and deliver CO_2 as desired for insufflation is similar to the predicate.

Principles of Operation
The principle of operation of providing a conduit to delivery gas for insufflation is similar to the predicate.

Non-clinical Testing
Bench Testing
Performance testing was conducted to ensure that the tubing does not affect the delivery pressure accuracy of the insufflator. The subject device was tested and met its performance acceptance criteria.

Animal Testing

Animal testing demonstrated that the tubeset device is compatible with the endoscope system, the tubeset remained attached to the endoscope during use, the device could be maneuvered as intended and did not cause any tissue injury during use.

Biocompatibility
Biocompatibility testing of the patient contacting materials included ISO 10993-5 - Cytotoxicity and ISO 10993-10 - Sensitization and Irritation as a Surface Contacting, Mucosal, Limited Duration of Use device.

Substantial Equivalence Conclusion
The comparison and testing demonstrate that the subject device is substantially equivalent to the predicate and that there are no new questions of safety or effectiveness raised when compared to the predicate.