July 24, 2026

VISION MEDICAL Co., Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
1887 Whitney Mesa Dr.
Suite 1960
Henderson, Nevada 89014

Re: K262152
Trade/Device Name: VS-370CF, VS-370CT
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FCX
Dated: June 25, 2026
Received: June 25, 2026

Dear Dave Yungvirt:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K262152

Device Name
VS-370CF, VS-370CT

Indications for Use *(Describe)*
The VS-370CT and VS-370CF are intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by filling it with gas.

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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K262152
510(k) Summary
VS-370CF, VS-370CT

Prepared in Accordance with 21 CFR 807.92

I. Submitter Information

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Date Prepared: 15 Jul 2026

II. Device Information

Trade or Proprietary Name:	VS-370CF, VS-370CT
Common or Usual Name:	CO_2 insufflators
Classification Name:	Endoscope and accessories (21 CFR 876.1500)
Regulatory Class:	Class II
Product Code:	FCX
Classification Panel:	Gastroenterology/Urology

III. Predicate Device

Device Name:	EVA5 INSUFFLACTOR (K230474)
Manufacturer:	Palliare Ltd.
Product Code:	FCX
Classification:	Class II (21 CFR 876.1500)

IV. Device Description

The VS-370CT and VS-370CF are intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by insufflating it with medical-grade carbon dioxide gas. These devices serve as gastrointestinal insufflation apparatus that facilitate endoscopic examination or visualization by distending the gastrointestinal lumen. The primary function is to inject CO_2 gas into the gastrointestinal

lumen to distend it, thereby enabling improved visualization and access for endoscopic instruments during gastrointestinal endoscopic procedures.

V. Indications for Use

The VS-370CT and VS-370CF are intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by filling it with gas.

VI. Technological Characteristics Comparison

	SUBJECT Device	**PRIMARY PREDICATE Device (K230474)**	**Significant Difference**
Manufacturer	VISION MEDICAL Co., Ltd.	Palliare Ltd.	–
Trade Name	VISION MEDICAL CO2 Insufflator VS-370CT/VS-370CF	EVA5 Insufflator	–
Regulation Description	Endoscope and accessories.	Endoscope And Accessories	No difference
Regulation Number	876.1500	876.1500	No difference
Product Code	FCX	FCX	No difference
Class	2	2	No difference
Intended Use/ Indications for Use	The VS-370CT and VS-370CF are intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by filling it with gas.	The EVA5 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by filling it with gas.	No difference
Fundamental Scientific Technology	Digital insufflation flow regulation system using compressed CO2 gas	Digital insufflation flow regulation system using compressed CO2 gas.	No difference
Patient Connection	Endoscope connection	Endoscope connection	No difference
Duration and Type of Contact	Indirect patient contact by CO2 gas	Indirect patient contact by CO2 gas	No difference
Distension Medium	CO2 gas	CO2 gas	No difference
Gas Delivery Modes	Fixed Flow	Fixed Flow	No difference
Flow Range	1.0-4.0 SLPM	0-4 SLPM	Difference
Dimensions (W×D×H)	300 × 360 × 132 mm (VS-370CF) 300 × 416 × 930 mm (VS-370CT)	160 × 130 × 330 mm	Difference
Weight	8.0 kg (VS-370CF) 20.0 kg (VS-370CT)	5.0 kg	Difference
Power source	100-240V	100-240V	No difference
User Interface	LCD Touch Screen	Membrane Panel	Difference
Automatic Switch-off time	Not applicable	30, 60, 90, 120 minutes	Difference

The comparison reveals minor differences that do not affect substantial equivalence. The flow range variation (VS-370CF/CT: 1.0-4.0 SLPM vs. EVA5: 0-4 SLPM) remains within clinically acceptable insufflation parameters. Physical differences in dimensions and weight represent non-critical variations that do not affect intended use, technological characteristics, or safe handling requirements in clinical settings. Interface differences between LCD touchscreen (subject devices) and membrane panel (predicate) do not impact clinical performance or safety, with both providing equivalent parameter input capabilities and visual feedback. The absence of automatic switch-off timer in subject devices introduces no new safety or effectiveness issues, as modern insufflator operators typically manage duration through direct control.

VII. Performance Data

1. Non-Clinical Testing

Comprehensive nonclinical testing was conducted to demonstrate substantial equivalence to the predicate device. Performance testing included electrical safety compliance with IEC 60601-1, electromagnetic compatibility testing per IEC 60601-1-2, and flow accuracy verification.

- Electrical Safety Testing:
  Both devices successfully passed electrical safety requirements per IEC 60601-1:2005+AMD1:2012+AMD2:2020 for Class II medical equipment.

- EMC Testing:
  Both devices demonstrated compliance with IEC 60601-1-2:2014+A1:2020 requirements for electromagnetic compatibility, including conducted and radiated emissions, and immunity to electromagnetic disturbances per CISPR 11 Class A.

- Flow Control Performance:
  Testing demonstrated flow accuracy within ±0.3 L/min tolerance across all nine discrete flow rate settings. System-level testing verified proportional flow control with real-time feedback from flow sensors maintains accurate delivery rates. Standby mode flow rate consistently measured as specified. Continuous uninterrupted gas output sustained for ≥60 seconds across all test conditions.

- Software Verification and Validation:
  Embedded software underwent comprehensive testing including unit-level testing, integration testing, and system-level validation. Risk management file testing verified implementation of risk control measures for identified software hazards including data integrity, timing accuracy, and hardware interaction control.

These nonclinical test results support a determination of substantial equivalence by demonstrating that both VS-370CF and VS-370CT devices perform as safely and effectively as the predicate EVA5 Insufflator within the same performance envelope and safety parameters.

2. Clinical Testing

No clinical data was required for this 510(k) submission. The determination of substantial equivalence is based on the identical intended use, equivalent technological characteristics, and comprehensive nonclinical performance data demonstrating equivalent safety and effectiveness to the legally marketed predicate device EVA5 Insufflator (K230474).

VIII. Substantial Equivalence Conclusion

Based on the comprehensive comparison and nonclinical testing, the VS-370CF and VS-370CT CO2 insufflators are substantially equivalent to the predicate EVA5 Insufflator (K230474). Both subject devices demonstrate the same intended use, employ identical fundamental scientific technology of digital insufflation flow regulation using compressed CO2 gas, and operate within equivalent performance parameters.

The nonclinical performance data confirms that both devices are as safe, as effective, and perform as well as the predicate device. Minor differences in physical configuration, user interface design, and flow range specifications do not raise new questions of safety or effectiveness and remain within clinically acceptable parameters for endoscopic insufflation procedures.

The comprehensive risk management analysis, software verification and validation, and performance testing demonstrate that the VS-370CF and VS-370CT provide the same level of safety and clinical benefit as the predicate device for their intended use in diagnostic and therapeutic endoscopic procedures requiring gastrointestinal tract distension with CO2 gas.