October 20, 2023

Motus GI Medical Technologies Ltd.
Mark Pomeranz
CEO and President
22 Keren Ha'yesod Str.
Tirat Carmel, 3902638
Israel

Re: K232922
Trade/Device Name: Pure-Vu EVS System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF, FDS
Dated: September 19, 2023
Received: September 19, 2023

Dear Mark Pomeranz:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
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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)*

K232922

Device Name
Pure-Vu EVS System

Indications for Use *(Describe)*

The Pure-Vu EVS System is intended to connect to standard or slim colonoscopes and gastroscopes to help facilitate intra-procedural cleansing of the GI tract by irrigating or cleaning and evacuating irrigation fluid (water), feces, and other bodily fluids and matter, e.g. blood.

It is for use only by trained medical personnel located in hospitals, clinics and doctors' offices.

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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510(k) Summary

This special 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Applicant Information:	Motus GI Medical Technologies Ltd. 22 Keren Ha'yesod Str. Tirat Carmel, 3902638 Israel Tel.: +972-4-6214446 Fax: +972-4-6214442
Contact Person:	Mark Pomeranz
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Establishment Registration #:	3011816755
Date Prepared:	September 19, 2023
Trade Name(s):	Pure-Vu EVS System
CommonName:	Pure-Vu EVS System
Classification Name:	Endoscope and accessories
Classification:	Regulation No: 876.1500 Class: II Panel: Gastroenterology and Urology
Predicate Device(s):	Pure-Vu System (K220007)
Reference Device:	Pure-Vu System (K210981)
Indications for Use:	The Pure-Vu EVS System is intended to connect to standard or slim colonoscopes and gastroscopes to help facilitate intra-procedural cleansing of the GI tract by irrigating or cleaning and evacuating irrigation fluid (water), feces, and other bodily fluids and matter, e.g. blood. It is for use only by trained medical personnel located in hospitals, clinics and doctors' offices.
Technological Characteristics:	The Pure-Vu EVS System enables cleaning of the GI tract during endoscopy using a standard or slim colonoscope with a length of 1630mm – 1710mm and an outer diameter range of 11.7mm – 13.2mm or gastroscope with a length of 950 – 1030mm and an outer diameter of 9.2 – 10mm The EVS Flex Channel , which fits alongside the endoscope and is connected to an external Workstation, generates fluid and gas to break up debris The debris & fluids are removed through the suction channel of the EVS Flex Channel into an external waste container/bag.

	The Pure-Vu EVS System consists of the following main components: • Disposable device which includes a **Flex Channel section** and an **Umbilical Section (US) -** The EVS Flex Channel fits alongside the endoscope to allow a physician to cleanse the GI tract and is connected to the external Workstation via a disposable US. • **Workstation (WS) –** The Workstation [WS] is reusable and supplies an irrigation mixture of water or saline and gas, and evacuates debris and fluids. The Workstation includes the following components: ○ A monitoring & Control Unit that controls the delivery of irrigation fluids and gas into the GI tract, and suction of fluid and matter from the GI tract. ○ Irrigation Bag/Bottle (saline or water) which is connected to the irrigation line. ○ Waste Containers for collecting the GI content & fluids that are suctioned from the GI tract through the suction lines. ○ Inlet Module that includes pumps and regulators enabling fluid & gas flow into the cleansing device. ○ Outlet Module that includes pumps to evacuate fluid and matter from the GI tract. ○ A foot pedal activates the cleansing, suction and purging functions, and enables switching between cleansing modes used by the physician.
Performance Data	Verification and Validation Testing tests were conducted for all modifications to the Pure-Vu EVS System component as follows: **1) Pure-Vu EVS Disposables** • Environmental conditioning/Shelf-life simulation: All disposable units underwent preconditioning simulations tests at third party laboratories including but not limited to environmental conditioning and shelf-life simulation to demonstrate that the Pure-Vu EVS Disposables functionality meets the requirements following a simulated aging of one year. • Dimensions test: Dimensional compliance of the disposables with the product specifications. • Head Pull test: Verification of minimum force that causes linear movement of the EVS DD flexible head relative to the endoscope • Steering test: Impact of the ability of the Pure-Vu EVS Flex Channel on an endoscope to bend in its distal steering section

	based on actuating the knobs on the handle of the colonoscope: • System test: Measurement of different pressure, air and water flow values in order to confirm that the system complies with product specifications. • Pressure test: Verification that the disposable withstands specific pressure without any leakage. • Bond strength test: Verification of the tensile force of the bonds in the disposable device. The disposable package underwent environmental conditioning and distribution simulation by third party laboratories in order to demonstrate the integrity of the packaging and their accompanying labels following the simulation. In addition, biocompatibility testing was done to determine if there was any toxicological risk to the patient. 2) **Pure-Vu EVS Workstation (WS)** The modified software of the WS underwent the following tests: • Software verification and validation for the software modifications. **3) System Validation Testing** Validation testing for the entire Pure Vu EVS system (WS and disposable devices) was performed with 6 physicians. Design verification and validation testing concluded that the design changes have no impact on the Pure-Vu System performance.
Substantial Equivalence Discussion:	The Pure-Vu EVS System has the same intended use, principles of operation and similar technological characteristics as its predicate and reference devices. The differences between the subject device and its predicate and reference devices due to the modifications as detailed in this submission do not raise any new issues of safety or effectiveness. Performance data demonstrate that the Pure-Vu EVS System is substantially equivalent.
Conclusion:	The Pure-Vu EVS System is substantially equivalent to the predicate and reference devices. The intended of use of this product meets the requirements of 21 CFR 801.4

A comparison of the subject and predicate devices is provided in the Table below.

	Subject Device	Predicate Device K220007
Manufacturer	Motus GI Medical Technologies Ltd.	
Description	Pure-Vu EVS System	Pure-Vu EVS System
Indications for Use	The Pure-Vu EVS System is intended to connect to standard or slim colonoscopes and gastroscopes to help facilitate intra-procedural cleansing of the GI tract by irrigating or cleaning and evacuating irrigation fluid (water), feces, and other bodily fluids and matter, e.g. blood. It is for use only by trained medical personnel located in hospitals, clinics and doctors' offices.	The Pure-Vu EVS System is intended to connect to standard and slim colonoscopes to help facilitate intra-procedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter, e.g. blood. It is for use only by trained medical personnel located in hospitals, clinics and doctor offices.
Environment of Use	Hospitals, clinics and doctors' offices	Hospitals, clinics and doctors' offices
Prescriptive	Same	Yes, only trained medical personnel
Technological Characteristics		
Disposable	Same	Single patient, single use
Distal tip design	Same as predicate with the exception that the hole geometry that fits on the endoscope was modified to allow it to be pushed on like an endoscopy cap.	1) Multi irrigation hole 2) One distal suction hole

	Subject Device	Predicate Device K220007
Principle of operation	Same as the predicate device with the exception of how the device connects to the endoscope. There is no longer a loading handle to connect the device to the endoscope as the distal head can just be pushed on the scope (like an endoscopy cap) and the low friction sleeve material is now only covering the dual lumen tubing and not the endoscope with 2 or 3 retainer strips to hold the dual lumen tube next to the endoscope.	Distal attachment to an endoscope using a loading handle, sleeve covering the tubing and endoscope ensuring attachment along entire length, dual lumen suction and irrigation tube running along the endoscope, suction and irrigation head at the distal tip. Enables irrigation and suction at any time during the procedure without removing any tools, which may be inserted in the endoscope's working channel.
Operational Procedures	1) Attachment to Standard or Slim colonoscope or gastroscope 2) Intra-procedure cleansing of GI tract during standard endoscopy 3) Evacuation of water, feces and matter	1) Attachment to a Standard or Slim colonoscope 2) Intra-procedure colon cleansing during standard colonoscopy 3) Evacuation of water and feces and other matter
Oversleeve / Flex Channel maximum outer diameter	21 mm Colon 18mm Gastro	21 mm Colon (distal head is the largest diameter)
Irrigation & suction system	Colon version: • same as predicate Gastro version: • Irrigation 3 nozzles (1 with 0.25 mm and 2 with 0.8 x 0.25mm mm	Irrigation: 5 nozzles x 0.6 mm Suction: 1 nozzle x 40 mm^2
Disposable length	167 cm attached to colonoscope 103 cm attached to gastroscope	167 cm attached to colonoscope
Air / Suction pressure specification	Air: Up to1.65 bar for Colon Version Up to 2.1 bar for Gasto version Suction specifications: (-)0.5 Bar for both	Up to1.65 bar (24psi) Suction specifications: (-)0.5 Bar

	Subject Device	Predicate Device K220007
Flow rate (cc / min)	Same	Water – Up to 645 cc/min Air – up to 1000 cc/min
Dimensions: Workstation:	Same	W250 mm \ D400mm \ H280 mm
Weight Workstation	Same	12Kg
Electrical Input	Same	100V-240V/50/60 Hz
Material	Same	Complies with ISO 10993
Sterilization	Same	Clean, Non-sterile
System Components	Same with the addition of the gastroscope Oversleeve now referred to as Flex Channel and a version to fit on gastroscopes	1) Pure-Vu Workstation 2) Pure-Vu Colon Oversleeves 3) Pure-Vu WS Connector (also, referred to as Umbilical section)
Safety Standards	Same	Complies with: IEC 60601-1 IEC 60601-1-2