February 10, 2022

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

Re: K220007
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
Dated: December 30, 2021
Received: January 4, 2022

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 (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,

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)*

K220007

Device Name
Pure-Vu EVS System

Indications for Use *(Describe)*

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.

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
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Establishment Registration #:	3011816755
Date Prepared:	December 30, 2021
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 (K191220)
Indications for Use:	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.
Technological Characteristics:	The Pure-Vu EVS System enables colon cleaning during colonoscopy using a standard or slim colonoscope with a length of 1630mm – 1710mm and an outer diameter range of 11.7mm – 13.7mm. The Oversleeve, which fits over the colonoscope and is connected to an external Workstation, generates fluid and gas to break up feces. The fecal matter & fluids are removed through the suction channel of the Oversleeve into an external waste container. The Pure-Vu EVS System consists of the following main components:

	• **Oversleeve (OS) and Umbilical Section (US) -** The disposable Oversleeve is mounted on Standard or Slim commercially available colonoscopes 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 fecal material 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 fluids and feces from the colon. ○ 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 disposable with the product specifications. • Steering test: Impact of the ability of the Pure-Vu EVS Oversleeve on a colonoscope 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 transport 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 WS underwent the following tests: • Environmental conditioning and transportation simulation performed by third party laboratories as per ASTM D4169, DC13. After the preconditioning simulations, the Pure-Vu EVS WS underwent verification testing including visual inspection and functionality tests. • The embedded updated software compliance with the WS design modifications was tested via software verification and validation. • Cleaning verification was performed to demonstrate compatibility with cleaning agents noted in IFU. • IPX2 per IEC 60529 • Dimension verification • Safety and EMC tests per IEC 60601 • Validation testing for the WS and disposable device was performed with 4 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 device. The differences between the device and its predicate device 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 device. 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.

Characteristics Comparison:		
	Modified Device	**Predicate Device**
Manufacturer	Motus GI Medical Technologies Ltd.	
Description	Pure-Vu EVS System	
Indications for Use	Same	The Pure-Vu 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	Same	Hospitals, clinics and doctors' offices
Prescriptive	Same	Yes, only trained medical personnel
Disposable	Same	Single patient, single use
Distal tip design	1) Same 2) One distal suction hole	1) Multi irrigation hole 2) Two distal suction holes
Principle of operation	Same except for 5 tubes in predicate versus one dual lumen tube in subject device.	Distal attachment to an endoscope, sleeve ensuring attachment along entire length, suction and irrigation tubes 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) Same 2) Same 3) Same	1) Attachment to a Standard or Slim colonoscope 2) Intra-procedure colon cleansing during standard endoscopy 3) Evacuation of water and feces
System Components	The Pure-Vu EVS System consists of the same main components as the predicate device with the minor modifications described in Section 9, Design Control Activities including the removal of the Pure-Vu Loading Fixture	1) Pure-Vu Workstation 2) Pure-Vu Standard and Slim colonoscope Oversleeves 3) Pure-Vu WS Connector 4) Pure-Vu Loading Fixture

Characteristics Comparison:		
	Modified Device	**Predicate Device**
Oversleeve outer diameter	Same	21 mm
Irrigation & suction system	Irrigation: 5 nozzle x 0.6 mm Suction: 1 nozzle x 40 mm^2	Irrigation: 4 nozzle x 0.7 mm Suction: 2 nozzles x 12.5 mm^2
Disposable length	Same	167 cm attached to colonoscope
Air / Suction pressure specification (bar)	Up to1.65 bar (24psi) Same	Up to 1.55bar (23 psi) Suction specifications: (-) 0.5 Bar
Flow rate (cc / min)	Water – Same Air – Up to 1000cc/min	Water - Up to 645 cc/min Air – up to 1350 cc/min
Dimensions Workstation	W250mm \ D400mm \ H280 mm	W250mm \ D476mm \ H358 mm
Weight Workstation	12Kg	18Kg
Electrical Input	Same	100V-240V 50/60 Hz
Material	Same	Complies with ISO 10993
Sterilization	Same	Clean, Non-sterile
Safety Standards	Same	Complies with: • IEC 60601-1 • IEC 60601-1-2