April 29, 2021

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

Re: K210981
Trade/Device Name: Pure Vu System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF, FDS
Dated: March 31, 2021
Received: April 1, 2021

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)*
K210981

Device Name
Pure Vu System

Indications for Use *(Describe)*
Pure-Vu System is intended to connect to standard or slim colonoscopes and gastroscopes to facilitate intra-procedural cleansing of the GI tract by irrigating and evacuating the irrigation fluids (water), bodily fluids and other debris, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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, 3902638Israel Tel.: +972-4-6214446 Fax: +972-4-6214442
Contact Person:	Mark Pomeranz
Phone Number:	908 745 8599
Fax Number:	972+733735181
Establishment Registration #:	3011816755
Date Prepared:	March 31, 2021
Trade Name(s):	Pure Vu System
CommonName:	Pure Vu 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:	Pure-Vu System is intended to connect to standard or slim colonoscopes and gastroscopes to facilitate intra-procedural cleansing of the GI tract by irrigating and evacuating the irrigation fluids (water), bodily fluids and other debris, e.g. blood. It is for use only by trained medical personnel located in hospitals, clinics and doctors' offices.
Technological Characteristics:	The Pure-Vu System enables cleansing of the digestive tract during endoscopy using a standard or slim colonoscope with a length of 1630mm – 1710mm and an outer diameter range of 11.7mm – 13.3mm (slim) and 12.8mm – 13.7mm (standard), or gastroscope with length of 950-1030mm and an outer diameter of 10mm – 10.9mm. The Oversleeve, which fits over 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 channels of the Oversleeve into an external waste container. The Pure-Vu 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 or gastroscopes 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/saline and gas, and evacuates bodily fluid and matter. The Workstation [WS] includes the following components: ○ A monitoring & Control Unit that controls the delivery of irrigation fluids and gas into the colon, and suction of bodily fluid and matter from the GI tract. ○ 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 function, and switch between cleansing modes used by the physician. • **Loading fixture-** The loading fixture is reusable and aids in assembling the Oversleeve onto the endoscope. • **Unloading aids -** A disposable luer lock syringe/ duckbill check valve assembly used in unloading the Oversleeve from the endoscope.
Performance Data	Verification and Validation Testing tests were conducted for all modifications to the Pure Vu System component as follows: • Steering test: Impact of the ability of the Gastro Oversleeve on a gastroscope to bend in its distal steering section based on actuating the knobs on the handle of the endoscope: ○ Acceptance criteria (same as for the predicate device) - The angle difference should be a maximum of 25% between a naked gastroscope and a gastroscope with an Oversleeve. • Head Pull Test: Verification of the linear movement between the Gastro Oversleeve head to the distal end of a gastroscope by simulating conditions similar to the withdrawal phase during colonoscopy procedure: ○ Acceptance criteria (same as for the predicate device) - Gastro Oversleeve shall not move linearly in relation to the gastroscope with less than 10N of force applied. • Loading and maintenance of pressure during the loading procedure of the Gastro Oversleeve using the Gastro Sealing plug onto a gastroscope to verify a successful loading procedure without creating any damage to the device or the scope: ○ Acceptance criteria – a. 100% successful loading procedures b. No damage to the flexible head identified by 100% visual inspection after the loading procedure

	c. Maintain pressure of up to 400 mBar d. No damage to the gastroscope in 100% of the loading procedures verified by examining images using the gastroscope's optics. 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 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 System is substantially equivalent.
Conclusion:	The Pure-Vu 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 System	
Indications for Use	The Pure-Vu System is intended to connect to standard or slim colonoscopes and gastroscopes to facilitate intra-procedural cleansing of the GI tract by irrigating and evacuating the irrigation fluids (water), bodily fluids and other debris, e.g. blood. It is for use only by trained medical personnel located in hospitals, clinics and doctors' offices.	The Pure-Vu System is intended to connect to standard 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 doctors' 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	Same	• Multi irrigation hole • Two distal suction holes
Principle of operation	Same	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) Attachment to a Standard and Slim colonoscope or gastroscope 2) Intra-procedure cleansing during standard endoscopy 3) Same	1) Attachment to a Standard and Slim colonoscope 2) Intra-procedure cleansing during standard colonoscopy 3) Evacuation of bodily fluids and matter

System Components	The Pure-Vu System consists of the same main components as the predicate device with the addition of the Gastro Oversleeve and the minor modifications described in Section 9, Design Control Activities	1) Pure-Vu Workstation 2) Pure-Vu Standard and Slim colonoscope Oversleeves 3) Pure-Vu WS Connector 4) Pure-Vu Loading Fixture
Oversleeve outer diameter	Same	21 mm
Irrigation & suction system	Same	Irrigation: 4 nozzle x 0.7 mm^2 Suction: 2 nozzles x 12.5 mm^2
Disposable length	Same for colonoscope 100 cm for gastroscope	167 cm attached to colonoscope
Air / Water pressure specification (bar)	Same Same	Up to 23 psi Suction specifications: - 0.5 Bar
Flow rate (cc / min)	Same	Water - Up to 645 cc/min Air – up to 1350 cc/min
Dimensions Workstation	W250mm \ D476mm (516 with pump head) \ H-358 mm	W460 \ D480 (520 with pump head) \ H340 mm
Weight Workstation	18Kg	25Kg
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