June 6, 2019

Motus GI Medical Technologies Ltd.
℅ Randy Prebula
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, DC 20004

Re: K191220
Trade/Device Name: Pure Vu System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF
Dated: May 4, 2019
Received: May 7, 2019

Dear Randy Prebula:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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.
Acting Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191220

Device Name
Pure Vu System

Indications for Use *(Describe)*
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 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, 3902638Israel Tel.: +972-4-6214446 Fax: +972-4-6214442
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Establishment Registration #:	3011816755
Date Prepared:	May 4st, 2019
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 (K181437)
Intended Use:	The Pure-Vu System is intended to connect to standard colonoscopes to help facilitate intra-proceduralcleaning 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.

Reason for Submission:	The purpose of this special 510(k) is to improve the overall ease of use of the Pure-Vu system by reduce the size and weight of the Work Station (WS) for better access in the procedure room and easier mobility. The fundamental scientific technology of the device remains unchanged. Modifications have been made as listed below: • Pure-Vu Workstation modifications to improve the usability of the system. The key improvements are reducing the size and weight of the WS, simplifying the evacuation algorithm during cleansing and improve the interface with the disposable Oversleeve. The embedded software was updated to comply with the WS design modifications. • Disposable Oversleeve modifications include extending the length of the hydrophilic lubricious coating from 60 cm to 80 cm on the distal end of the Pure-Vu Oversleeve to enhance advancement, Outer and inner sleeves are made of 80A durometer polyurethane as opposed to combination of 80A and 70A durometer polyurethane and added an In-Line connector to ease management and assembly of the Umbilical tubing. All manufacturing locations and key processes remain the same. • The loading fixture was modified to reduce its size and weight. The sealing clamp and plug used on the distal end of the device was modified to be a one-piece assembly that is now disposable to improve ease of loading. No new materials were introduced and there were no modifications to the compressor box (the only electrical assembly part of the fixture) that generates the inflation pressure used to open the sleeve for loading. In addition, the unloading process is performed with the disposable sealing clamp as opposed to an off the shelf Kelly clamp used for unloading in the predicate device.

Technological Characteristics:	The Pure-Vu System enables colon cleansing during colonoscopy using a standard or slim colonoscope with a length of 1630mm – 1710mm and a slim colonoscope outer diameter range of 11.7mm – 13.3mm and a standard colonoscope outer diameter range of 12.8mm – 13.7mm. The Oversleeve, which fits over the colonoscope and is connected to an external Workstation, generates fluid to break up feces. The fecal matter & fluids are removed through the suction channels of the Oversleeve into an external waste receptacle. 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 to allow a physician to cleanse the colon 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 fecal material & fluids. The Workstation [WS] includes the following components: o A monitoring & Control Unit that controls the delivery of irrigation fluids and gas into the colon, and suction of fluids and feces from the colon. o Inlet Module that includes pumps and regulators enabling fluid & gas flow into the cleansing device. o Outlet Module that includes pumps to evacuate fecal matter and fluids from the colon. o 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 colonoscope. • **Unloading aids -** A disposable 60cc lure lock syringe and 3-way stopcock used in unloading the Oversleeve from the colonoscope are provided in the disposable packaging.

Performance Data:	Verification and Validation Testing tests were conducted for all modifications to the Pure Vu System component as follows: 1) Pure- Vu Disposable parts (Oversleeve and Workstation connector) All disposable units undergone preconditioning simulations tests performed by Carmel Environmental Laboratory (Israel) including but not limited to Environmental conditioning and Shelf life simulation to demonstrate that the Pure Vu Disposables functionality meets the requirements following a simulated aging of one year. Simulation (bench test) was conducted and to support the sub system and system's use as intended and its substantial equivalence as follows: • Dimensions Test • Steering (Angulation) • System Test • Pressure Test • Bond Strength Test Disposable package undergone environmental conditioning and transport simulation (by DDL labs) in order to demonstrate efficiency and 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 as per ISO 10993-5. 2) Pure-Vu Workstation (WS) The Modified WS undergone the following tests: • Environmental conditions and distribution cycle simulation performed by Hermon Laboratory (Israel) as per ASTM D4169-16 along with shipping integrity. After the preconditioning simulations, the Pure Vu WS undergone verification testing including visual inspection and functionality tests. • The embedded updated software to comply with the WS design modifications was tested via software validation. • Safety and EMC tests per IEC 60601 • Usability and validation testing for the WS and disposable device has been performed in two separate studies with 3 physicians and 15 nurses. 3) Pure-Vu Loading and Unloading • Validation testing for the new sealing plug used during loading and unloading was performed. • Environmental conditions and distribution cycle simulation performed by DDL (USA) as per ASTM D4169-16 along with shipping integrity. After the preconditioning simulations, the Pure Vu WS undergone verification testing including visual inspection and functionality tests. 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, indications, 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

Characteristics Comparison:		
-	**Modified Device**	**Predicate Device**
Manufacturer	Motus GI Medical Technologies Ltd.	
Description	Pure-Vu System	
Intended Use	Same	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
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) Same 2) Same 3) Same	1) Attachment to a standard and Slim colonoscope 2) Intra-procedure colon cleansing during standard colonoscopy 3) Evacuation of water and feces
System Components	The Pure-Vu System consists of the same main components as the predicate device but each one has had minor modifications. The detailed information on the modifications done to each of the system component please refer to: 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	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