December 12, 2017

Motus GI Medical Technologies Ltd.
% Hagit Ephrath
VP of Health Economics, Regulatory and Clinical Affairs
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: K173392
Trade/Device Name: Pure Vu System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: December 6, 2017
Received: December 8, 2017

Dear Hagit Ephrath:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173392

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
Contact Person:	Hagit Ephrath
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Establishment Regist.:	3011816755
Date Prepared:	October 26th, 2017
Trade Name(s):	Pure-Vu System
CommonName:	Pure-Vu System
Classification Name:	Endoscope and accessories
Classification:	Regulation No: 876.1500Class: II Panel: Gastroenterology and Urology
Predicate Device(s):	Pure-Vu System (K160015)
Intended Use:	The Pure-Vu System is intended to connect to standard colonoscopes to help facilitate intra-procedural cleansing 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 modify the Pure Vu System by: 1) Simplifying the process of unloading the colonoscope by using disposable materials rather than an Unloading Fixture 2) Minor material modifications to the Oversleeve and Workstation Connector, 3) Minor modifications to Workstation, and Loading Fixture components 4) Minor software modifications 5) Modify slight the air/water specifications

Technological Characteristics:	The Pure-Vu system comprises the following components: **Oversleeve** - The Oversleeve is mounted on standard commercially available colonoscopes allowing thephysician to clean the colon. **Workstation (WS)** - The Workstation operates by usingcyclic irrigation and evacuation of colon content. Irrigationis based on mixture of liquid and air. The workstation includes: • Monitoring & Control Unit that continuouslymonitors and controls irrigation and evacuation. • Inlet Module that includes pumps and regulatorsenabling water & airflow into the cleansing device. • Outlet Module that includes pumps to evacuatefecal matter and fluids from the colon. • External on\off foot pedals that operate thecleansing process to be used by the physician. **WS Connector (WSC)** connects the Oversleeve to the WS and saline or water bag. **Loading fixture** to aid the nurse in mounting the Oversleeve on to a colonoscope.
Performance Data:	Performance tests were conducted for all modifications to the Pure-Vu System. Specifically, the company performed the following performance tests: • Biocompatibility • Electrical Safety and EMC • Software validation • Bench tests o Bond strength o Pressure test o System test o Steering test In all instances, the Pure-Vu System functioned as intended.
Substantial Equivalence Discussion:	The Pure-Vu System has the same indications and similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the Pure-Vu System and its predicate devices do not raise different 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.

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 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
Operational Procedures	Same; Simplified procedure to unload the colonoscope	• Attachment to a standard colonoscope • Intra-procedure coloncleansing during standard colonoscopy • Evacuation of water and feces
System Components	• "Add-on" name change to "Oversleeve" • "WS Cartridge" name change to "WS Connector"	• Pure-Vu Add-on • Pure-Vu WS Cartridge
Oversleeve outer diameter	Same	21 mm

-	Modified Device	Predicate Device
Irrigation & suction system	Same	Irrigation: 4 nozzle x 0.7 mm Suction: 2 nozzles x 12.5 mm^2
Disposable length	Same	167 cm attached to colonoscope
Air / Water pressure specification (bar)	Up to 23 psi Same	Up to 26 psi Suction specifications: 0.5 Bar
Flow rate (cc / min)	Water - Up to 645 cc/min Air – Same	Water - Up to 630 cc/min Air – up to 1350 cc/min
Dimensions Workstation	Same	W460 \ D 520 \ H340 mm
Weight Workstation	Same	25Kg
Electrical Input	Same	100V-240V 50/60 Hz
Material	Minor material modifications Re-tested to ISO 10993	Complies with ISO 10993
Sterilization	Same	Clean, Non-sterile
System Components	Motus GI Workstation Motus GI Oversleeve Loading Fixture	Motus GI Workstation Motus GI Add-on Loading Apparatus Unloading Apparatus
Safety Standards	Minor component modifications Re-tested to: IEC 60601-1; IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2