June 21, 2018

Motus GI Medical Technologies Ltd.
Hagit Ephrath
VP of Health Economics, Clinical and Regulatory Affairs
22 Keren Ha'yesod St.
Tirat Carmel, 3902638
ISRAEL

Re: K181437
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 31, 2018
Received: June 1, 2018

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 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,

Timothy Martin -S
2018.06.21 15:35:36 -04'00'

for
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)*
K181437

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.

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

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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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Fax Number:	+972-4-6214442
Establishment Regist.:	3011816755
Date Prepared:	May 31st, 2018
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 (K173392)
Intended Use:	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.
Reason for Submission:	The purpose of this special 510(k) is to modify the Pure Vu System to comply with Slim colonoscope. Modifications include the followings: 1) Add SLIM Oversleeve which is a modification of the Oversleeve design including narrowing the inner dimensions of the flexible head and leaf seal of the inflation hub. 2) Revision of the IFU including adding reference to the Pure-Vu SLIM, specify the range of colonoscope diameters for Pure-Vu and Pure-Vu SLIM disposables. 3) Add SLIM Seal plug to the Loading Fixture to enable loading with the revised SLIM Oversleeve. In addition, the Oversleeves hydrophilic coating was extended to 60cm to enhance advancement.

Technological Characteristics:	The Pure Vu system comprises the following components: **Oversleeve** - The Oversleeve is mounted on Standard or Slim commercially available colonoscopes to allow a physician to cleanse the colon. **Workstation (WS)** - The Workstation operates by using simultaneous irrigation and evacuation of colon content. Irrigation is based on a mixture of liquid (water or saline) and gas (air). The workstation includes: • Monitoring & Control Unit that continuouslymonitors and controls irrigation and evacuation. • Inlet Module that includes pumps and regulatorsenabling fluid & gas flow into the cleansing device. • Outlet Module that includes pumps to evacuate fecal matter and fluids from the colon. • External foot pedals that control the cleansing process to be operated by a 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 onto a colonoscope.
Performance Data:	Performance tests were conducted for all modifications to the Pure Vu System. Specifically, the company performed the following bench tests: • Steering test • Head pull test • Loading and maintenance of pressure during the loading procedure
Substantial Equivalence Discussion:	The Pure Vu System has the same indications and similar technological characteristics and principles of operation as its predicate device. Expending the variety of colonoscopes to be used with the Pure-Vu System and the minor differences between the device and its predicate device 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.

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
Operational Procedures	1) Attachment to a standard and Slim colonoscopes 2) Same 3) Same	1) Attachment to a standard colonoscope 2) Intra-procedure coloncleansing during standard colonoscopy 3) Evacuation of water and feces
System Components	1) Pure-Vu Workstation (Same) 2) Pure-Vu Standard Oversleeve (Same) or Motus GI SLIM Oversleeve 3) Pure-Vu WS Connector (Same) 4) Pure-Vu Loading Fixture (Same)	1) Pure-Vu Workstation 2) Pure-Vu Oversleeve 3) Pure-Vu WS Connector 4) Pure-Vu Loading Fixture
Oversleeve outer diameter	Same	21 mm

-	Modified Device	Predicate Device
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	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	Same	W460 \ D 520 \ H340 mm
Weight Workstation	Same	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