DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 22, 2016

Motus GI Medical Technologies Ltd.
% Jonathan S. Kahan
Partner
Hogan Lovells US LLP
Columbia Square, 555 13th Street, NW
Washington, DC 20004

Re: K160015
Trade/Device Name: Pure Vu System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: August 22, 2016
Received: August 22, 2016

Dear Jonathan S. Kahan:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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)*
K160015

Device Name

Pure Vu System

Indications for Use *(Describe)*

The Pure Vu System is intended to connect to standard colonoscopes to help facilitate intraprocedural 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 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.

Submitter Name and Address:		Motus GI Medical Technologies Ltd. 22 Keren Ha'yesod Str. Tirat Carmel, 3902638 Israel Tel.: +972-4-6214446 Fax: +972-4-6214442
Contact Person:		Hagit Ephrath
Phone Number:		+972-4-6214447 ext. 104
Fax Number:		+972-4-6214442
Establishment Registration Number:		K160015
Date Prepared:		December 31, 2015
Device Trade Name(s):		Pure Vu System
Device Common Name:		Pure Vu System
Classification Name:		Endoscope and accessories
Classification:		Regulation No: 876.1500 Class: II Panel: Gastroenterology and Urology
Predicate Device(s):		ClearPath Lower GI (manufactured by EasyGlide Ltd. and the subject of 510(k) documents no. K113050)

General Device Description:		The Pure Vu system comprises the following components: **Add-on** - The Add-on is mounted on standard commercially available colonoscopes allowing the physician to clean the colon. **Workstation (WS)** - The Workstation operates by using cyclic irrigation and evacuation of colon content. Irrigation is based on mixture of liquid and air. The workstation includes: • Monitoring & Control Unit that continuously monitors and controls irrigation and evacuation. • Inlet Module that includes pumps and regulators enabling water & airflow into the cleansing device. • Outlet Module that includes pumps to evacuate fecal matter and fluids from the colon. • External on\off foot pedals that operate the cleansing process to be used by the physician. **WS Cartridge (WSC)** connects the Add on to the WS and saline or water bag. **Loading fixture** to aid the nurse in mounting the Add-on to a colonoscope. **Unloading fixture** to aid the nurse in removing the Add-on from a colonoscope.
Indications for Use:		The Pure Vu System is intended to connect to standard colonoscopes to help facilitate intraprocedural 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 system intended use, principle of operation and basic scientific technology are substantially equivalent to the ClearPath Lower GI (K113050). Both are connected to distal standard colonoscope during colonoscopy procedure and irrigate the colon and evacuate the irrigation fluid (water), feces, and other bodily fluids and matter, e.g. blood. Both enable irrigation and suction at any time during the procedure without removing any toolswhich may be inserted in the colonoscope working channel. Both devices have similar

		dimensions of the disposable, with similar irrigation and evacuation head on the top of the colonoscope.
Substantial Equivalence Discussion		Comparison between Pure Vu System and its predicate device regarding the intended use, principle of operation, basic technological characteristics, biocompatibility and their level of cleansing was conducted. It is concluded that Pure Vu System is as safe and effective as the ClearPath Lower GI (K113050). The Pure Vu System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Pure Vu System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Pure Vu System is as safe and effective as the ClearPath Lower GI. Thus, the Motus GI System is substantially equivalent.
Performance Data:		Performance tests were conduct to verify that the Pure Vu System meets the requirements for its intended use and is substantial equivalence to the predicate device. **Biocompatibility** The Pure Vu Add-on is a surface contact device with a limited contact (shorter than ≤24 hours) of the mucosal tissue. The Pure Vu WS Cartridge (WSC) is an externally communicating devices with a limited contact (shorter than ≤24 hours) of the mucosal tissue. As such, the following biocompatibility tests were performed: • Cytotoxicity: Growth Inhibition Test - Extraction Method • Irritation: Intracutaneous Reactivity Test • Sensitization: Skin sensitization All materials and representative manufacturing processes of the disposable kits passes the above tests and were found biocompatible. **Electrical Safety and EMC** The Pure Vu System includes a workstation which controls irrigation and evacuation through the disposable attached to the colonoscope. In addition the System accessories, Loading and Unloading fixtures, includes inflation boxes enabling to mount the Add-on to a colonoscope prior to the clinical procedure and to remove the Add-on from a colonoscope after the procedure.

		All 3 System components are designed and constructed to conform with the IEC 60601-1 and 60601-1-2 medical electrical equipment safety standard. The System components were tested for mechanical and electrical safety and are found as compliant with the IEC 60601-1 and 60601-1-2. **Software validation** Pure Vu software has been validated per EC 62304:2006, Medical Device Software and followed the companies Software Life-Cycle Processes. **Bench tests** Performance tests after preconditioning were conducted and included the following aspects of the product: Bound strength test, Pressure test, overall System performance, Add-on movement, and steering segment abilities. Bench test results confirm that the Pure Vu System meets its requirements for its intended use. **Pure Vu System – Animal study:** A prospective animal study was conducted to establish the effectiveness and safety of Pure Vu. The final configuration of Pure Vu System was used in 35 procedures in swine (66% female) performed by 4 experienced gastroenterologists. No immediate, such as mucosal injury, or delayed adverse events were reported in any of the 35 animal procedures. In 30/35 (86%) of the procedures, the colon cleansing level prior the use of the Pure Vu device was inadequate, whereas 100% (35/35) of the animals had an excellent colon cleansing level following the use of Pure Vu. The physicians were satisfied with the Pure Vu ease of advancement and navigation, level of stiffness, and its torque response. They found Pure Vu easy to use and intuitive to operate. Pure Vu was found to be simple, safe and effective to be used.

Conclusion:		Based on the technological characteristics and pre-clinical performance of the device, Motus GI medical Technologies Ltd. believes that the Pure Vu System and the predicate device selected are substantially equivalent and do not raise new issues of safety or effectiveness.