DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 11, 2016

GI View Ltd.
% Mark Heller
Partner
Goodwin Procter LLP
901 New York Avenue, NW
Washington, D.C. 20001

Re: K161791
Trade/Device Name: Aer-O-Scope Colonoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: June 30, 2016
Received: June 30, 2016

Dear Mark Heller:

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.
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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)*
K161791

Device Name

Aer-O-Scope Colonoscope System

Indications for Use *(Describe)*

The Aer-O-Scope Colonoscope System is intended to provide panoramic (360o) visualization (via a video monitor) and diagnostic/therapeutic access to the adult lower gastrointestinal tract, (including but not limited to, the anus, rectum, sigmoid colon, transverse colon, cecum and ileocecal valve) for endoscopy.

The Aer-O-Scope Disposable Scanner (colonoscope component of the Aer-O-Scope Colonoscope System) is a single use disposable device. An Aer-O-Scope Scanner cannot be reprocessed.

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

Owner: GI View Ltd.

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Summary Date: February 4, 2016

Device Name, 21 CFR 807.92(a)(2)

Trade Name: Aer-O-Scope Colonoscope System

Common Name: Colonoscope

Classification Name: Endoscope and accessories, 21 CFR § 876.1500

Product Code: FDF

Predicate Device, 21 CFR 807.92(a)(3):

Trade Name: Invendo C20 Colonoscopy System

510(k) Number: K100624 and K121582

Common Name: Colonoscope

Classification Name: Endoscope and accessories, 21CFR 876.1500

Product Code: FDF

Predicate Device, 21 CFR 807.92(a)(3):

Trade Name: Aer-O-Scope Colonoscope System

510(k) Number: K141286

Common Name: Colonoscope

Classification Name: Endoscope and accessories, 21CFR 876.1500

Product Code: FDF

Device Description, 21 CFR 807.92(a)(4)
The Aer-O-Scope Colonoscope System subject to the 510(k) Premarket Notification and the Aer-O-Scope predicate device share the same name and hereafter will be distinguished by referring to as **Aer-O-Scope 1 (the predicate)** and **Aer-O-Scope 2 (the new device).**

The Aer-O-Scope 2 is a flexible, operator-controlled, colonoscope that utilizes a propulsion mechanism to provide visualization and therapeutic access to the colon. It is comprised of two major components, the Controlling Work Station and the Aer-O-Scope 2 Disposable Scanner (the colonoscope component). The work station system console contains all components and subsystems required for operation and control of the Aer-O-Scope Colonoscope System, including a joystick component for controlling scope tip deflection. The Aer-O-Scope 2 Disposable Scanner includes a soft narrow multi-lumen tube with channels for irrigation, insufflation, therapeutic access and suction, CO_2 delivery to the balloons and colon and the soft balloons for the propulsion system. The Disposable Scanner also includes an optical imaging head with a CMOS sensor and lenses for both forward visualization and a 360° panoramic omni view. All commands are controlled by the operator and regulated through the Controlling Work Station.

The Aer-O-Scope 2 utilizes a propulsion system for colonic intubation and scanning. The propulsion system relies on CO_2 gas and soft pliable balloons that allow the Aer-O-Scope 2 scanner to travel through the colon without the need for pushing force. The tip of the scope with the optical imaging head can be deflected in any direction to ensure full visualization. This propulsion system is identical to the Aer-O-Scope 1 Colonoscope System.

The Aer-O-Scope 2 Colonoscope System contains optional post processing spectral filtering capabilities that assist the physician in examining features captured in standard white light colonoscopy images.

The Aer-O-Scope 2 Disposable Scanner is a single use device and cannot be reprocessed. The main materials that come in contact with the patient are polyurethane and Pebax™ that are coated with a hydrophilic coating. The Aer-O-Scope 2 Disposable Scanner is biocompatible according to the ISO 10993 harmonized and FDA consensus standard.

Predicate Comparison, 21 CFR 807.92(a)(6)

The Aer-O-Scope 1 Colonoscope System was deemed substantially equivalent to the predicate Invendo C20 Colonoscopy System in the 510(k) clearance letter for the Premarket Notification 510(k) number K141286.

The substantial equivalence determination applies to the Aer-O-Scope 2 insofar as its technological features are the same as those of the Aer-O-Scope 1. In terms of those technological characteristics that differ between the Aer-O-Scope 1 and the Aer-O-Scope 2, GI View submitted bench testing to show that these differences in technological characteristics do not affect the substantial equivalence determination, i.e., the Aer-O-Scope 2 is also substantially equivalent to the Invendo C20 Colonoscopy System.

The focus of this Premarket Notification 510(k) is the Aer-O-Scope 2's indication that, like the Invendo C20 Colonoscopy System indication, includes diagnostic/therapeutic access.

The Invendo C20 Colonoscopy System and the Aer-O-Scope 2 Colonoscope System have the same indications for use for visualization and diagnostic/therapeutic access. The Aer-O-Scope 1's indications are a subset of the Aer-O-Scope 2's indications in that Aer-O-Scope 1 is indicated for visual but not diagnostic/therapeutic access.

The Aer-O-Scope 1, Aer-O-Scope 2 and the Invendo C20 all have the same intended use, i.e., providing access, illumination, and allowing observation or manipulation of body cavities, hollow organs, and canals, see 21 CFR § 876.1500. All three systems are indicated for adult populations who may undergo colonoscopy in physicians' clinics, ambulatory surgical centers and hospital settings.

Indications for Use Comparison:

Aer-O-Scope 2 Colonoscope System *Indications for Use Statement*	**Invendo C20 Colonoscopy System (K100624 & K121582)** *Indications for Use Statement*	**Aer-O-Scope 1 Colonoscope System (K141286)** *Indications for Use Statement*
The Aer-O-Scope Colonoscope System is intended to provide panoramic (360°) visualization (via a video monitor) and diagnostic/therapeutic access to the adult lower gastrointestinal tract, (including but not limited to, the anus, rectum, sigmoid colon, transverse colon, cecum and ileocecal valve) for endoscopy. The Aer-O-Scope Disposable Scanner (colonoscope component of the Aer-O-Scope Colonoscope System) is a single use disposable device. An Aer-O-Scope Scanner cannot be reprocessed.	The Invendo C20 Colonoscopy System is intended to provide visualization and diagnostic/therapeutic access to the adult lower gastrointestinal tract (including but not limited to, the anus, rectum, sigmoid colon, transverse colon, cecum and ileocecal valve) for endoscopy and endoscopic surgery. The colonoscope component of the Invendo C20 Colonoscopy System, the SC20 colonoscope, is a single use disposable device. The SC20 colonoscope cannot be reprocessed.	The Aer-O-Scope Colonoscope System is intended to provide panoramic (360°) visualization (via a video monitor) and visual access to the adult lower gastrointestinal tract, (including but not limited to, the anus, rectum, sigmoid colon, transverse colon, cecum and ileocecal valve) for endoscopy. The Aer-O-Scope Disposable Scanner (colonoscope component of the Aer-O-Scope Colonoscope System) is a single use disposable device. An Aer-O-Scope Scanner cannot be reprocessed.

Performance Data – Bench, 21 CFR 807.92(b)(1):

GI View Ltd. conducted bench tests to measure forces during device use, biocompatibility of device components and safety. In all instances the Aer-O-Scope 2 Colonoscope System functioned as intended and met the individual test specifications.

Biocompatibility tests were performed and met all of the required criteria.

EMC and Electrical safety were tested and found compliant with the applicable standards.

Ex-vivo studies were performed to demonstrate the ability to provide therapeutic access to the lower bowel.

Pre-clinical *in vivo* tests in swine were performed to demonstrate overall safety and efficacy.

Performance Data – Clinical, 21 CFR 807.92(b)(2);

No clinical data is needed for the determination of substantial equivalence. The predicate Aer-O-Scope 1 Colonoscope System Premarket Notification (K141286) included a clinical section demonstrating the performance of the system as related to cecal intubation. The Aer-O-Scope 2 device utilizes the identical propulsion system for colonic intubation; therefore there was no need for further clinical performance data for the determination of substantial equivalence.

Summary, 21 CFR 807.92(b)(3);

The bench tests included studies related to forces, biocompatibility, constructive and electrical safety and demonstrated that the Aer-O-Scope 2 Colonoscope System performed as well as the predicate devices. The data also demonstrated that the Aer-O-Scope 2 Colonoscope System can successfully provide a simple visualization tool and therapeutic access to the lower gastrointestinal tract for screening endoscopy (colonoscopy).