August 17, 2023

GI View Ltd.
% Kristin Davenport
Partner
Covington & Burling LLP
One City Center, 850 Tenth St, NW
Washington, DC, District of Columbia 20001-4956

Re: K230588
Trade/Device Name: Aer-O-Scope Colonoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: July 17, 2023
Received: July 18, 2023

Dear Kristin Davenport:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 -S

Shanil P. Haugen, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230588

Device Name
Aer-O-Scope Colonoscope System

Indications for Use *(Describe)*
The Aer-O-Scope Colonoscope System is intended to provide 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 colonoscope is a single use disposable endoscope and 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Owner: GI View Ltd.

Address: 5 Shoham St.
5251001 Ramat Gan
Israel

Contact: Sharon Goldfarb
VP Regulatory and Clinical
Phone: +972-54-6454034
Fax: +972-3-761-7974
Email: Sharon@giview.com

Summary Date: March 1, 2023

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

Trade Name: Aer-O-Scope Colonoscope System[1]

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: Evis Exera II 180 System

510(k) Number: K100584

Common Name: Endoscopic Video Imaging System

Classification Name: Endoscope and accessories, 21 CFR 876.1500

Product Code: NWB, FDF, FDS

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

[1] The Aer-O-Scope Colonoscope System subject to the 510(k) Premarket Notification and the Aer-O-Scope Reference device share the same name and hereafter will be distinguished by referring to as ***Aer-O-Scope 2*** **(**the Reference K161791) and **Aer-O-Scope 3** (the device subject to this 510(k) submission).

Trade Name: Aer-O-Scope Colonoscope System (2)

510(k) Number: K161791

Common Name: Colonoscope

Classification Name: Endoscope and accessories, 21 CFR 876.1500

Product Code: FDF

Device Description, 21 CFR 807.92(a)(4)
The Aer-O-Scope 3 Colonoscope System is a flexible, operator-controlled, colonoscope that provides visualization and therapeutic access to the colon. It is comprised of two major components, the Video Controller and the Aer-O-Scope 3 Disposable Colonoscope. The Video Controller contains all components and subsystems required for operation and control of the Aer-O-Scope 3 Colonoscope System. The Aer-O-Scope 3 Disposable Colonoscope includes channels for irrigation, insufflation, lens wash, therapeutic access, and suction. The disposable colonoscope includes an optical imaging head with a CMOS sensor and lenses for visualization with a 200° panoramic omni field of view. All commands are controlled by the operator and regulated through the Video Controller.

The Aer-O-Scope 3 Disposable Colonoscope is a single use device and cannot be reprocessed. The main material that comes in contact with the patient is polyurethane that is coated with a biocompatible hydrophilic coating. The Aer-O-Scope 3 Disposable Colonoscope is biocompatible according to the ISO 10993 harmonized and FDA consensus standard.

Predicate Comparison, 21 CFR 807.92(a)(6)
The main technological and operational features of the Aer-O-Scope 3 (other than the visualization system) are the same as those of the Evis Exera II 180 System (Evis Exera II Video System Center Olympus CV-180 (*"CV-180"*) & Evis Exera II Colonovideoscope Olympus CF type H180AL (*"CF H180AL"*)). The only differences between the Aer-O-Scope 3 and the predicate relate to visualization (including a CMOS chip and LED lighting) and disposability and the hydrophilic coating, features that are also present in the Aer-O-Scope Colonoscope System 2 (reference device). GI View submitted data from the *Aer-O-Scope 2 Colonoscope System* for the visualization, hydrophilic coating & disposability features, as well as performance testing to show that the technological differences between the Aer-O-Scope 3 and the predicate do not affect the substantial equivalence determination.

The Aer-O-Scope 3 Colonoscope System has a subset of the indicated uses and associated technological and operational characteristics of the predicate Olympus Evis Exera II 180 System (the indication for the Olympus device also includes surgery). Both devices are indicated for adult populations who may undergo colonoscopy in physicians' clinics, ambulatory surgical centers, and hospital settings.

While operationally the same as the Olympus predicate device, the technology differs in that the Aer-O-Scope 3 uses a CMOS chip and LED lighting and the Olympus predicate uses a CCD chip and fiber optic lighting.

Like the predicate, the Aer-O-Scope 3 Disposable Colonoscope is a long flexible endoscope with optics at the deflectable tip of the device and openings for irrigation, insufflation, and suction. The Aer-O-Scope 3's Video Controller supplies and controls the Aer-O-Scope Disposable Colonoscope according to user command inputs via a touchpad (on the Video Controller) or buttons on the colonoscope handle, similar to the Olympus predicate. The distal tip deflection of both the device subject to this Premarket Notification and the predicate are controlled by angulation knobs on the scope handles. The Aer-O-Scope 3 utilizes a CMOS image sensor and LEDs incorporated directly into the distal tip of the Aer-O-Scope Disposable Colonoscope; whereas the CCD image sensor and Xenon light source of the Olympus predicate are external, and signals are carried over fiber optics. Like the predicate, the Aer-O-Scope 3 Colonoscope System is equipped with insufflation, irrigation, lens wash and suction.

Hydrophilic coating and predefined variable stiffness along the insertion tube are incorporated into the Aer-O-Scope 3 to facilitate colonic intubation. The Olympus CF H180AL Colonoscope has an operator controlled variable stiffness mechanism to facilitate colonic intubation. While the mechanisms for colonic intubation facilitation are different, both methods have shown to be successful for streamlining colonic intubation. These differences do not affect the safety and effectiveness of the Aer-O-Scope 3 compared to the predicate.

Indications for Use Comparison:

Aer-O-Scope 3 Colonoscope System ***Indications for Use Statement***	**Evis Exera II 180 System** **(K100584)** ***Indications for Use Statement***	*(Reference)* ***Aer-O-Scope 2 Colonoscope System*** ***(K161791)*** ***Indications for Use Statement***
The Aer-O-Scope (3) Colonoscope System is intended to provide visualization (via a video monitor) & 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 colonoscope is a single use disposable endoscope and cannot be reprocessed.**	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE H180AL, These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, Endotherapy accessories (such as a biopsy forceps), and other ancillary equipment **for endoscopy and endoscopic** **surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon,** **and ileocecal valve**).	*The Aer-O-Scope (2) Colonoscope System is intended to provide panoramic (360°)* ***visualization (via a video monitor) & 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.*

Performance Data – Bench, 21 CFR 807.92(b)(1):
GI View Ltd. conducted packaging and shelf-life testing which met all the criteria.

Biocompatibility tests were performed and met all the required criteria.

EMC and Electrical safety were tested (voluntary ASCA Pilot) and found compliant with the applicable standards.

Bench tests to measure the safety and effectiveness of device components were performed.

Bench tests to measure optical parameters and safety such as photobiological safety, resolution and geometric distortion were performed.

In all instances the Aer-O-Scope 3 Colonoscope System functioned as intended and met the individual test specifications and/or FDA consensus standards.

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

Performance Data – Clinical, 21 CFR 807.92(b)(2);
Clinical data support the determination of substantial equivalence. A clinical investigation was performed to demonstrate safety and effectiveness of cecal intubation and the performance of the Aer-O-Scope Colonoscope System 3. The data demonstrated that the Aer-O-Scope 3 Colonoscope System (with a wider field of view (200°) compared to the predicate) successfully allows cecal intubation in the intended use population and provides therapeutic access to the lower gastrointestinal tract for screening, diagnostic and surveillance endoscopy (colonoscopy) as the predicate devices.

Summary, 21 CFR 807.92(b)(3);
The bench tests included studies related to forces, biocompatibility, optical performance and constructive and electrical safety. The tests demonstrated that the Aer-O-Scope 3 Colonoscope System performed as expected and met the specifications/FDA consensus standards requirements. As such, the bench tests demonstrated the Aer-O-Scope 3 performed as well as the predicate devices. The data also demonstrated that the Aer-O-Scope 3 Colonoscope System successfully provided a wider field of view (200°) as well as therapeutic access to the lower gastrointestinal tract for screening, diagnostic and surveillance endoscopy as other colonoscopes.