August 21, 2026

Gi View, Ltd.
℅ Amit Goren
RA Consultant
A. Stein - Regulatory Affairs Consulting , Ltd.
18 Hataas St. (Suite 19)
Kfar Saba, 4442518
Israel

Re: K261015
Trade/Device Name: Solo Scope Colonoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF, FET
Dated: July 21, 2026
Received: July 21, 2026

Dear Amit Goren:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SIVAKAMI VENKATACHALAM -S

for
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261015

Please provide the device trade name(s).

Solo Scope Colonoscope System

Please provide your Indications for Use below.

The Solo 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 Solo Scope Disposable colonoscope is a single use disposable endoscope and cannot be reprocessed.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(K) SUMMARY

SOLO SCOPE COLONOSCOPE SYSTEM

510(k) Number K261015

Applicant Name:

Company Name: GI-View Ltd.

Address: 5 Shoham St.
Ramat Gan, 5251001
Israel
Tel: +972-58-4534373
E-mail: oded@giview.com

Contact Person:

Official Correspondent: Amit Goren

Company Name: A. Stein – Regulatory Affairs Consulting Ltd.

Address: 18 Hata'as Str.,
Kfar Saba 4442518, Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: April 21, 2026

Trade Name: Solo Scope Colonoscope System

Classification Name: 21 CFR 876.1500

Product Codes: FDF, FET

Classification: Class II

Predicate Device:

The subject device is substantially equivalent to the following predicate device:

Manufacturer	Device	510(k) No.
GI-View Ltd.	Aer-O-Scope Colonoscope System	K230588

Device Description:

The Solo Scope Colonoscope System consists of a video controller and a disposable, single-use colonoscope. Like the predicate, the Solo Scope Colonoscope System is a long flexible endoscope with optics at the deflectable tip of the device and openings for irrigation, insufflation, lens washing, and suction.

The Solo Scope's Video Controller controls the Solo Scope Colonoscope according to user command inputs via either a touchscreen (on the Video Controller) or buttons on the colonoscope handle. The distal tip is deflectable and controlled by angulation knobs on the handle.

The device maintains insertion behavior, handling, and performance characteristics comparable to conventional colonoscopes. The colonoscope unit is intended for single use, eliminating the need for colonoscope reprocessing.

Intended Use/Indication for Use:

The Solo 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 Solo Scope Disposable colonoscope is a single-use, disposable endoscope and cannot be reprocessed.

The intended use is identical to that of the predicate device.

Technological Characteristics and Comparison to Predicate:

The Solo Scope Colonoscope System shares the same intended use and indications for use as the predicate Aer-O-Scope Colonoscope System and is based on comparable technological principles.

Where applicable, comparative testing was conducted against the predicate device to support substantial equivalence.

The subject and predicate devices share comparable technological characteristics, including the same fundamental device components (video controller and disposable colonoscope), mechanism of operation, user interface and operation methods, and applicable safety and performance requirements.

The technological differences between the predicate and subject devices include:

• Video Controller (VC) core system architecture:

  – Processor change (Intel-based PC → Nvidia AGX Orin)

  – Operating system change (Windows → L4T, Ubuntu-based)

• Colonoscope design modifications:

  – Insertion tube variable stiffness mechanism (predefined → physician-controlled adjustable stiffness)

  – Modifications to mechanical, electro-optical, and packaging components

The technological differences do not raise new or different questions of safety or effectiveness. The technological differences were evaluated through comprehensive verification and validation testing, including mechanical, optical, electrical, and software performance testing, as well as biocompatibility and environmental evaluations.

The results of these evaluations demonstrate that the subject device meets all predefined acceptance criteria and performs comparably to the predicate device.

The methods used to evaluate these differences are consistent with those applied to the predicate device, including biocompatibility, electrical and EMC safety testing, software validation, and bench testing of mechanical and optical performance.

The Solo Scope Colonoscope System maintains insertion behavior, handling characteristics, and visualization performance that perform comparably to conventional colonoscopes and within the validated performance envelope of the predicate device.

Verification testing was conducted using established methods aligned, to the extent appropriate, with those previously applied to the predicate device.

The evaluation was based on comparable test methodologies and predefined acceptance criteria derived from validated predicate device verification protocols and corresponding performance specifications.

The identified technological differences were evaluated through risk-based design controls and verification activities and were determined not to raise new questions of safety or effectiveness.

Non-Clinical (Bench) Performance Data:

The following validation activities were performed:

- Software Verification and Validation Testing
- Cybersecurity Verification and Validation Testing
- Electrical safety and EMC testing
- Biocompatibility evaluation
- Mechanical Testing
- Optical and Colorimetric Testing
- Environmental, transportation, and shelf-life Testing

All of the validation activities were performed using the same testing techniques and principles as those used with the predicate device. The results of the above-listed validation activities demonstrate that the subject device meets predefined acceptance criteria and supports substantial equivalence to the predicate device.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Conclusions:

Based on the information provided, including bench, software, and safety testing, the Solo Scope Colonoscope System is substantially equivalent to the predicate device, the Aer-O-Scope Colonoscope System (K230588).