April 11, 2022

Smart Medical Systems Ltd.
℅ Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, PA 19103

Re: K220158
Trade/Device Name: G-EYE System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF
Dated: January 19, 2022
Received: January 19, 2022

Dear Janice Hogan:

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,

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

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)*

K220158

Device Name

G-EYE® System

Indications for Use *(Describe)*

The G-EYE® colonoscope is intended to be used with a compatible video processor (including light source), documentation equipment, monitor, endotherapy device such as a biopsy forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the lower gastrointestinal tract including the anus, rectum, sigmoid colon, colon and ileocecal valve. It incorporates a balloon at the distal end of the colonoscope to maintain central positioning within the lumen and help control the endoscope's view field and/or endoscope positioning.

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

SMART Medical Systems Ltd.'s G-EYE® System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: January 19, 2021

Name of Device

G-EYE® System

Common or Usual Name

Endoscope and accessories, Gastroenterology-Urology

Classification

21 CFR 876.1500, Class II, product code FDF

Predicate Devices

G-EYE® System (Predicate Device K202469)

G-EYE® System (Reference Device K192588)

Intended Use / Indications for Use

The G-EYE® Colonoscope is intended to be used with a compatible video processor (including light source), documentation equipment, monitor, endotherapy device such as a biopsy forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the lower gastrointestinal tract including the anus, rectum, sigmoid colon, colon and ileocecal valve. It incorporates a balloon at the distal end of the colonoscope to maintain central positioning within the lumen and help control the endoscope's view field and/or endoscope's positioning.

Device Description

The G-EYE® System comprises the G-EYE® Colonoscope and the NaviAid™ SPARKC ("SPARKC") inflation pump. The G-EYE® Colonoscope includes a reprocessable, reusable balloon (the G-EYE® balloon) that is attached to a standard, commercially available colonoscope which is remanufactured by Smart Medical to include the balloon at its bending section. The installation of the balloon onto the standard colonoscope is considered

remanufacturing of the standard colonoscope by Smart Medical, which assumes responsibility for the final device including the G-EYE® balloon and the remanufactured colonoscope. The G-EYE® balloon is inflated by the dedicated SPARKC inflation system, which enables automatic control of the required balloon pressure in one of several user-selected, system-controlled pressure levels such that the balloon conforms to the colonic lumen diameter. The G-EYE® Colonoscope is advanced by the endoscopist with the balloon deflated, which essentially preserves the standard colonoscope's diameter and insertion technique. At the cecum, the balloon is inflated to engage the colon walls, and the colonoscope is then withdrawn by the endoscopist using standard withdrawal technique. Withdrawal of the inflated balloon mechanically straightens the colonic folds and anatomic flexures, centers the colonoscope optics within the colonic lumen, and minimizes uncontrolled bowel slippage during withdrawal, therefore maintaining the endoscope's field of view

Technological Characteristics

The G-EYE® System is nearly identical to the previously cleared version of the device ("Predicate Device") (K202469). Both the subject device and Predicate Device have the same indications for use and principles of operation and substantially similar technological characteristics and materials.

The subject device and Predicate Device are both multi-use and intended to be reprocessed. Similar to the predicate, the G-EYE® Colonoscope is reprocessed in accordance with the reprocessing instructions of the original endoscope manufacturer with supplemental instructions related to the G-EYE® balloon. The current submission solely expands the range of endoscope models. This difference does not raise different questions of safety and effectiveness, as confirmed by the company's reprocessing validation testing.

The materials of the G-EYE® Colonoscope are substantially similar to those of the Predicate Device, and any differences in the materials of the G-EYE® Colonoscope and the predicate device do not raise different questions of safety or effectiveness. This was confirmed through the company's biocompatibility testing and performance testing.

Both the G-EYE® System and the Predicate Device feature a standard colonoscope. All compatible colonoscopes are 510(k) cleared and have an insertion tube diameter of 11.0mm – 13.2mm. The primary difference between the G-EYE® Colonoscope of the G-EYE® System and the G-EYE® colonoscope of the Predicate Device is the underlying standard colonoscope model, as noted above. As all standard colonoscopes underlying the G-EYE® Colonoscopes are 510(k) cleared colonoscopes, the minor differences among the standard colonoscopes included in the G-EYE® System and in the Predicate Device do not raise new questions of safety and effectiveness, and the difference does not adversely impact performance, as confirmed by the company's performance testing.

Performance Data

In support of this 510(k) premarket notification, Smart Medical conducted nonclinical testing to evaluate the performance of the G-EYE® System for its intended use. The performance testing conducted includes the following:

- Reprocessing validation testing consistent with FDA's guidance in *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*.

- Biocompatibility of patient-contacting components has been established in accordance with ISO 10993-1.
- Software verification and validation was performed, and demonstrated that the software performs as intended.
- Electrical safety and electromagnetic compatibility testing was conducted and results were passing in accordance with IEC 60601-1 and IEC 60601-1-2.
- Verification bench testing of the SPARKC and G-EYE® Colonoscope which included operational and functional testing.

Each of these tests met its acceptance criteria, supporting substantial equivalence to the predicate.

Although not required to demonstrate substantial equivalence, clinical data is available from five clinical studies that further support the safety and performance of the device for its intended use. In total, the studies included approximately 4500 subjects. All five studies demonstrated that the device functioned as intended, with no serious device-related adverse events. In addition, the studies demonstrated that the device served its intended function, and that the mechanical straightening of the colonic folds and anatomic flexures provided by the G-EYE® System facilitates visualization of the colonic mucosa surface area.

Substantial Equivalence

The G-EYE® System and its Predicate Device have the same intended use, same indications, same principles of operation, and similar technological characteristics. The minor technological differences do not present different questions of safety or effectiveness than the Predicate Device, and accepted scientific methods exist to evaluate the performance of the G-EYE® System compared to its Predicate Device. Performance data has demonstrated that the G-EYE® System is as safe and effective as its predicate. Thus, the G-EYE® System is substantially equivalent to the previously cleared G-EYE® System (K202469).