August 7, 2026

Intuitive Surgical, Inc.
Einav Yemini
Regulatory Technical Lead
1266 Kifer Rd.
Sunnyvale, California 94086

Re: K253702
Trade/Device Name: Intuitive Endoluminal Gastrointestinal System (IG1000)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FET
Dated: July 6, 2026
Received: July 7, 2026

Dear Einav Yemini:

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.	K253702

Please provide the device trade name(s).

Intuitive Endoluminal Gastrointestinal System (IG1000)

Please provide your Indications for Use below.

The Intuitive Endoluminal Gastrointestinal (GI) System is intended for the robotic-assisted control of the Robotic GI Endoscope during visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach and duodenum.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) 1990 and 21 CFR 807.92.

Submitter

510(k) Owner: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Einav Yemini
Regulatory Technical Lead
Intuitive Surgical, Inc.
1266 Kifer Road, Sunnyvale, CA 94086
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Date Prepared: June 29, 2026

Subject Device Information

Manufacturer Name:	Intuitive Surgical, Inc.
Trade Name:	Intuitive Endoluminal Gastrointestinal System (IG1000)
Common Name:	Endoscope and Accessories
Classification:	Class II, 21 CFR 876.1500
Product Code:	FDS, FET
Review Panel:	Gastroenterology/Urology

Predicate Device

FUJIFILM Medical Systems U.S.A., Inc. Endoscope Model EI-740D/S (K210162)

Reference Device

1. Intuitive Surgical, Inc. Ion Endoluminal System, Model IF1000 (K182188)
2. Olympus Medical Systems Gastrointestinal Videoscope GIF-1100 (K222584)

Device Description

The Intuitive Endoluminal Gastrointestinal (GI) System (IG1000) is a physician-controlled, electro-mechanical system intended to assist qualified physicians to navigate a GI endoscope and 3rd party endoscopic tools (placed or used through the working channels of the endoscope) in the upper GI tract using endoscopic visualization of the esophagus, stomach, and duodenum for observation, diagnosis, and therapeutic procedures. It consists of a System Cart, Motion Controller, Fluids System, Robotic GI Endoscope (RGE), and accessories.

The System Cart contains the Flexible Instrument Manipulator, electronics for the follower portion of the servomechanism, and a monitor. It allows the user to navigate the Robotic GI endoscope using the Motion

Controller and a leader/follower control system. For optimal viewing, the physician can position and orient the System Cart monitor in both the vertical and horizontal axes. The Fluids System resides on top of the System Cart and controls and directs the flow of gases and fluids for suction, irrigation, insufflation, and lens wash from their sources and through the endoscope in response to commands from the user through the Motion Controller.

The Motion Controller is the user input device for the system. It provides controls to command insertion, retraction, and articulation of the RGE via a scroll wheel, track ball, and roll ring. It also has buttons and a foot pedal to control fluidics functions (lens wash, insufflation, suction, and irrigation). Lastly, it includes a passive button to enter passive mode and an emergency stop button to enter a Safe Fault Reaction Logic (FRL) state.

The Robotic GI Endoscope is a 13.2mm OD flexible endoscope with a working length of 1030 mm. It contains integrated vision, illumination light fibers, shape sensing, 3.7 and 2.8 mm working channels compatible with third party endoscopic tools, and channels for irrigation, lens wash, insufflation, and suction.

Intended Use/Indications for Use

The Intuitive Endoluminal Gastrointestinal (GI) System is intended for the robotic-assisted control of the Robotic GI Endoscope during visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach and duodenum.

Comparison of Technological Characteristics with the Predicate Device

The subject device (IG1000 system) and predicate device (FUJIFILM EI-740D/S) are both intended for visualization during gastrointestinal procedures. They share overall the same functions of providing access, navigation, visualization, allowing control of the Endoscope tip, providing a working channel for endoscopic instruments, and enabling use of insufflation, irrigation, lens wash and suction. The differences between the subject and predicate devices are in their mode of operation and endoscope controls, software-enabled functionality and slight differences in dimensions, articulation and visualization. A summary of the technological characteristics of the subject device compared to the predicate device is provided below

Table 0-1: Comparison of the Subject and Predicate Devices

Description	Subject Device	Predicate Device (K210162)
Manufacturer	Intuitive Surgical Inc.	FUJIFILM Medical Systems U.S.A., Inc.
Trade Name	Intuitive Endoluminal Gastrointestinal System (IG1000)	Endoscope Model EI-740D/S
Common Name	Endoscope and Accessories	**Identical** to the subject device
Regulation Number	876.1500	**Identical** to the subject device

Description	Subject Device	Predicate Device (K210162)
Product Code	FDS, FET	FDS, FAM
Intended Use / Indications for Use	The Intuitive Endoluminal Gastrointestinal (GI) System is intended for the robotic-assisted control of the Robotic GI Endoscope during visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach and duodenum.	FUJIFILM Endoscope Model EI-740D/S is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum. This device is also intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and sigmoid colon.
Endoscope Working Length	1030 mm	**Identical** to the subject device
Distal End Diameter	15 mm	12.8 mm
Flexible Portion Diameter	13.2 mm	12.8 mm
Working Channels	Two- 3.7 & 2.8 mm	Two- 3.7 & 3.2 mm
Bending Angles	Minimum of 200° in all four directions	Up 210° Down 90° Left 100° Right 100°
Viewing Direction	0°	**Identical** to the subject device
Field of View	120°	140°
Observation Range	3mm - 100mm	**Identical** to the subject device

Performance Data

The following performance testing was conducted to demonstrate substantial equivalence to the predicate device.

Biocompatibility of the IG1000 system was evaluated in accordance with ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2023, ISO 10993-11:2018, ISO 10993-12:2021, ISO 10993-17:2023, and ISO 10993-18:2020, along with FDA Guidance “Use of International Standard ISO 10993-1, ‘Biological

evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'", issued on September 8, 2023.

Software verification and validation included unit, subsystem integration, and system level testing. The software testing results demonstrate that the IG1000 System Software meets design specifications and user needs. Software documentation has been provided per FDA Guidance "Content of Premarket Submissions for Device Software Functions," issued on June 14, 2023.

Cybersecurity testing included cybersecurity verification and validation, evaluated per the FDA's final guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", issued on September 27, 2023. The cybersecurity verification and validation test results demonstrate the adequacy of the implemented cybersecurity controls.

Electrical safety and electromagnetic compatibility testing was conducted using third-party labs in accordance with the current versions of IEC 60601-1 (basic safety and essential performance), IEC 60601-1-2 (electromagnetic disturbances), IEC 60601-2-18 (endoscopic equipment), IEC 80601-2-77 (robotically assisted surgical equipment) and IEC 60825-1 (laser safety).

Bench testing demonstrates that the IG1000 System's design output meets the design input requirements and that the system performs as intended. The testing conducted consisted of dimensional measurements, mechanical and functional verification, summative usability testing, and reprocessing, sterility, and shelf-life testing.

Animal and cadaver testing was performed for the evaluation of the safety and performance of the IG1000 system and software. Testing consisted of Design Validation and performance and safety equivalence testing, compared to the predicate device. The Design Validation studies evaluated the IG1000 System's intended use, safety, reachability, and performance. The performance and safety equivalence study evaluated the performance and safety of the IG1000 System compared to the predicate device, during its intended use of visualization of the upper digestive tract to support observation, diagnosis, and therapeutic procedures.

Clinical data was collected via a prospective, single center, single arm confirmatory clinical study. The study enrolled 28 subjects for indicated diagnostic, therapeutic, and surveillance procedures. Subjects were followed for 30 days. All study procedures were completed as planned with no conversions to manual endoscopy and no device-related serious adverse events through 30 days post-procedure. Results from the study demonstrate that the IG1000 System can safely access key anatomical locations throughout the Upper GI tract to enable diagnostic, therapeutic and/or surveillance procedures and confirm the safety and performance profile established through pre-clinical testing.

Conclusion

Based on the intended use, indications for use, technological characteristics, and performance data, the Intuitive Endoluminal Gastrointestinal (GI) System (Model IG1000) is substantially equivalent to its predicate device, the FUJIFILM Endoscope Model EI-740D/S.