May 9, 2025

Iterative Health
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K251126
Trade/Device Name: SKOUT system
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP
Dated: April 11, 2025
Received: April 11, 2025

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251126

Device Name

SKOUT system

Indications for Use *(Describe)*

The SKOUT system is a software device designed to detect potential colorectal polyps in real time during colonoscopy examinations. It is indicated as a computer-aided detection tool providing colorectal polyps location information to assist qualified and trained gastroenterologists in identifying potential colorectal polyps during colonoscopy examinations in adult patients undergoing colorectal cancer screening or surveillance.

The SKOUT system is only intended to assist the gastroenterologist in identifying suspected colorectal polyps and the gastroenterologist is responsible for reviewing SKOUT suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment. SKOUT is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make a primary interpretation of endoscopic procedures, medical diagnosis, or recommendations of treatment/course of action for patients. SKOUT is indicated for white light colonoscopy only.

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

SKOUT® system

K251126

Submitter Contact Information:

Address: Iterative Health, Inc. (Iterative Scopes)
14 Arrow Street Floor 3
Cambridge, MA 02138

Phone: (617) 209-9773

Contact: Caitlyn Seidl, VP, Scientific and Commercial Affairs

Date Prepared: April 29, 2025

Name of Device: SKOUT® system

Classification Name: Gastrointestinal lesion software detection system (21 CFR 876.1520, Product Code QNP)

Predicate Device: SKOUT® system, Iterative Scopes, K240781

Device Description

The SKOUT® system is a software-based computer aided detection (CADe) system for the analysis of high-definition endoscopic video during colonoscopy procedures. The SKOUT® system is intended to aid gastroenterologists with the detection of potential colorectal polyps during colonoscopy by providing an informational visual aid on the endoscopic monitor using trained software that processes the endoscopic video in real time.

Users will primarily interact with the SKOUT® system by observing the software display, including the polyp detection box and device status indicator signal.

Polyp Detection Notification

The SKOUT® system has a main graphical user interface (GUI) feature of the polyp detection notification. The polyp detection notification is a two-dimensional blue rectangular outline generated around any suspected polyps on the endoscopic video feed. If there is no polyp detected, the bounding box does not appear. SKOUT® system pauses polyp detection when an endoscopic tools are detected in the video feed to ensure that the bounding box does not hinder any surgical procedure, biopsy, or resection or this may also occur when lighting conditions are deemed to be inadequate.

The polyp detection notification enables users to:

- Detect potential colorectal polyps during colonoscopy examinations in adult patients undergoing a colorectal cancer screening or surveillance procedure.
- Utilize a tool that provides additional information for endoscopic observation.

Device Status Indicator

The SKOUT® system has an additional GUI feature that notifies users of the current device status (active or error):

- a two-dimensional green box with letter (S) when the device is powered on and actively processing video.
- a two-dimensional gray box with letter (S) when a surgical tool is present.
- a red (X) with an error message; when there is an error with the video processing function of the SKOUT® system, the green box will be replaced with a red X and error message to indicate an error has occurred.

Intended Use / Indications for Use

The SKOUT® system is a software device designed to detect potential colorectal polyps in real time during colonoscopy examinations. It is indicated as a computer-aided detection tool providing colorectal polyps location information to assist qualified and trained gastroenterologists in identifying potential colorectal polyps during colonoscopy examinations in adult patients undergoing colorectal cancer screening or surveillance.

The SKOUT® system is only intended to assist the gastroenterologist in identifying suspected colorectal polyps and the gastroenterologist is responsible for reviewing SKOUT® suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment. SKOUT® is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make a primary interpretation of endoscopic procedures, medical diagnosis, or recommendations of treatment/course of action for patients. SKOUT® is indicated for white light colonoscopy only.

Summary of Technological Characteristics

The subject device is a modified version of the predicate device, which was cleared on July 3, 2024 (K241508). The key characteristics of the subject SKOUT® system and the predicate SKOUT® system are compared in the following table.

Table 1: Comparison of Key Characteristics

	SKOUT® system (Subject Device, K251126)	**SKOUT® system (Predicate Device, K241508)**	**Comparison**
Device Version	SKOUT® system v2.2	SKOUT® system v2.1	N/A
Hardware Configuration(s)	SKOUT211 SKOUT220	SKOUT210	N/A
Regulation	21 CFR 876.1520	21 CFR 876.1520	Same
Product Code	QNP	QNP	Same
Device Class	Class II	Class II	Same
Intended Use	A gastrointestinal lesion software detection system is a computer-assisted detection device used in conjunction with endoscopy for	A gastrointestinal lesion software detection system is a computer-assisted detection device used in conjunction with endoscopy for	Same

	SKOUT® system (Subject Device, K251126)	SKOUT® system (Predicate Device, K241508)	Comparison
	the detection of abnormal lesions in the gastrointestinal tract. This device with advanced software algorithms brings attention to images to aid in the detection of lesions. The device has hardware components to support interfacing with an endoscope.	the detection of abnormal lesions in the gastrointestinal tract. This device with advanced software algorithms brings attention to images to aid in the detection of lesions. The device has hardware components to support interfacing with an endoscope.	
Indications for Use	The SKOUT® system is a software device designed to detect potential colorectal polyps in real time during colonoscopy examinations. It is indicated as a computer-aided detection tool providing colorectal polyps location information to assist qualified and trained gastroenterologists in identifying potential colorectal polyps during colonoscopy examinations in adult patients undergoing colorectal cancer screening or surveillance. The SKOUT® system is only intended to assist the gastroenterologist in identifying suspected colorectal polyps and the gastroenterologist is responsible for reviewing SKOUT® suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment. SKOUT® is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make a primary interpretation of endoscopic procedures, medical diagnosis, or recommendations of treatment/course of action for patients. SKOUT® is indicated for white light colonoscopy only.	The SKOUT® system is a software device designed to detect potential colorectal polyps in real time during colonoscopy examinations. It is indicated as a computer-aided detection tool providing colorectal polyps location information to assist qualified and trained gastroenterologists in identifying potential colorectal polyps during colonoscopy examinations in adult patients undergoing colorectal cancer screening or surveillance. The SKOUT® system is only intended to assist the gastroenterologist in identifying suspected colorectal polyps and the gastroenterologist is responsible for reviewing SKOUT® suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment. SKOUT® is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make a primary interpretation of endoscopic procedures, medical diagnosis, or recommendations of treatment/course of action for patients. SKOUT® is indicated for white light colonoscopy only.	Same

	SKOUT® system (Subject Device, K251126)	SKOUT® system (Predicate Device, K241508)	Comparison
User Population	Adult patients undergoing colorectal cancer screening or surveillance colonoscopy.	Adult patients undergoing colorectal cancer screening or surveillance colonoscopy.	Same
Fundamental Technological Characteristics	The SKOUT® system is composed of a single piece hardware design and software designed to highlight portions of the colon where the device detects potential colorectal polyps.	The SKOUT® system is composed of a single piece hardware design and software designed to highlight portions of the colon where the device detects potential colorectal polyps.	Same
Software Algorithm	The SKOUT® system utilizes an artificial intelligence-based algorithm to perform the polyp detection function.	The SKOUT® system utilizes an artificial intelligence-based algorithm to perform the polyp detection function.	Same
Power Source	Hospital mains power	Hospital mains power	Same
Safety Features	The Mode Selection Button allows for instantaneous toggling between the SKOUT® video feed and the bypass video feed in the event of software error that affects video quality. The polyp detection marker is disabled if a biopsy tool enters the field of view to prevent obstruction of the area of interest during intervention. SKOUT® system GUI also has a device status indicator that notifies users of the current device status (active or error): ● a two-dimensional green box with letter (S) when the device is powered on and actively processing video. ● a two-dimensional gray box with letter (S) when a surgical tool is present. ● a red (X) with an error message; when there is an error with the video processing function of the SKOUT® system, the	The Mode Selection Button allows for instantaneous toggling between the SKOUT® video feed and the bypass video feed in the event of software error that affects video quality. The polyp detection marker is disabled if a biopsy tool enters the field of view to prevent obstruction of the area of interest during intervention. SKOUT® system GUI also has a device status indicator that notifies users of the current device status (active or error): ● a two-dimensional green box with letter (S) when the device is powered on and actively processing video. ● a two-dimensional gray box with letter (S) when a surgical tool is present. ● a red (X) with an error message; when there is an error with the video processing function of the SKOUT® system, the	Same, except for minor change in internal hardware components for the video bypass switch. This change does not raise different questions of safety or effectiveness.

	SKOUT® system (Subject Device, K251126)	SKOUT® system (Predicate Device, K241508)	Comparison
	green box will be replaced with a red X and error message to indicate an error has occurred.	green box will be replaced with a red X and error message to indicate an error has occurred.	
Device Output	SKOUT® system generates markers in the form of blue rectangles superimposed on the endoscopic video when potential colorectal polyps are identified. SKOUT® markers are not accompanied by a sound. The polyp detection marker is disabled if a biopsy tool enters the field of view to prevent obstruction of the area of interest during intervention.	SKOUT® system generates markers in the form of blue rectangles superimposed on the endoscopic video when potential colorectal polyps are identified. SKOUT® markers are not accompanied by a sound. The polyp detection marker is disabled if a biopsy tool enters the field of view to prevent obstruction of the area of interest during intervention.	Same
Video Input	Serial Digital Interface (SDI); de-interlacing applied during pre-processing	Serial Digital Interface (SDI); de-interlacing applied during pre-processing	Same
Compatible Video Processors	Olympus EVIS EXERA II, Olympus EVIS EXERA III, and FUJIFILM Eluxeo VP-7000 with compatible HD output	Olympus EVIS EXERA III and FUJIFILM Eluxeo VP-7000 with compatible HD output	Addition of Olympus EVIS EXERA II video processor was validated in testing and does not raise different questions.
Video Delay	Video delay due to marker annotation = 0ms (no standard error; all results were 0, minimum resolution 1.1ms) Video delay due to device = 0ms (no standard error; all results were 0, minimum resolution 1.1ms)	Video delay due to marker annotation = 0ms (no standard error, all results were 0, minimum resolution 1.1ms) Video delay due to device = 0ms (no standard error, all results were 0, minimum resolution 1.1ms)	Same
Pixel Level Degradation	No pixel level degradation is introduced by SKOUT® to the Endoscopic System.	No pixel level degradation is introduced by SKOUT® to the Endoscopic System.	Same

The subject device includes the following minor changes to the technological characteristics compared to the predicate device:

- Introduction of alternate hardware configuration with modified GPU and video bypass switch to improve supply chain stability, reduce power consumption by the GPU, and reduce risk of hardware-related failure for bypass switch;
- Updates to system software to be compatible with both hardware configurations;
- Updates to back-end software (non-user facing);
- Update to the overheating warning message performance;
- Routine software updates to address bugs, cybersecurity, and code optimization identified by software maintenance activities;
- Additional video processing tower validated as compatible and added to the device labeling.

Performance Testing

Non-clinical performance testing was conducted to demonstrate that the SKOUT® system is as safe and effective as the predicate device.

- Electrical safety, usability and electromagnetic compatibility testing was conducted for the alternate hardware configuration per IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18, and IEC 60601-1-6.
- Software verification and validation testing was conducted to confirm the SKOUT® system software meets design requirements for its intended use, per the device's design documentation in line with recommendations outlined in General Principles of Software Validation, Guidance for Industry and FDA Staff.
- Algorithm performance testing was performed for evaluation of true positives, false positives, and polyp detection time, with an expanded dataset for the added video processing tower.
- Additional bench software testing was performed to confirm the device meets the special controls in 21 CFR 876.1520 for pixel degradation and video delays.

SKOUT® system demonstrated passing results in all applicable testing.

Conclusions

The SKOUT® system has the same intended use, indications for use, technological characteristics, and principles of operation as its predicate device. The minor differences in hardware and software do not affect its safety and effectiveness when used as labeled. The inference algorithms have remained the same, therefore clinical performance remains unchanged from the clinical testing submitted in K213686. Performance data demonstrates that the SKOUT® system is as safe and effective as the predicate device. Thus, the SKOUT® system is substantially equivalent.