April 7, 2023

Iterative Scopes Inc.
Dennis Francoeur
Director of Regulatory Affairs
675 Massachusetts Ave
2nd Floor
Cambridge, MA 02139

Re: K230658
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: March 9, 2023
Received: March 9, 2023

Dear Dennis Francoeur:

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)*

K230658

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)*

X 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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VII. 510(K) SUMMARY

510(k) SUMMARY

SKOUT® system

Submitter:

Iterative Health, Inc. (Iterative Scopes)

675 Massachusetts Ave

Cambridge MA 02139

Phone: (603) 819-8387

Contact Person: Dennis Francoeur, Director of Regulatory Affairs

Date Prepared: March 9, 2023

Name of Device: SKOUT® System

Classification Name: Gastrointestinal Lesion Software Detection System

Classification Panel: Gastroenterology and Urology

Regulation Number: 876.1520

Product Code: QNP

Predicate Device: SKOUT System, Iterative Scopes, K213686

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.

Design Changes

Hardware architecture changes: The multi piece tethered system of the predicate was updated to a single box containing all of the components. Some of the components included in the subject device have been updated to improve component longevity and image quality performance.

Software architecture changes: To support the updated hardware design the software was updated in addition to improvements to image handling for image quality performance and error handling for improved usability performance**.**

Non-Clinical Testing

- Software verification and validation was conducted on the changes to the SKOUT System software to validate it for its intended use per the design documentation in line with recommendations outlined in General Principles of Software Validation, Guidance for Industry and FDA Staff. The SKOUT software demonstrated passing results on all applicable testing.
- Electrical Safety Electromagnetic Compatibility the SKOUT system was evaluated for compliance to the following FDA-Recognized Consensus Standards:
    - IEC 60601-1:2005, AMD 1:2012 - Medical electrical equipment – Part 1: General requirements for basic requirements for basic safety and essential performance

- IEC 60601-1-2: 2014 - Medical electrical equipment – Part 1-2: General requirements for basic requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-2-18: 2009 - Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of endoscopic equipment

- Human factors validation was performed following the FDA Guidance document *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and FDA Staff recommendations*. The human factors validation demonstrated that the device functioned as intended, use-related risk has been mitigated, and the SKOUT system is safe for its intended use.

Summary of Technological Characteristics

The predicate device represents a previous revision of the subject device, SKOUT System FDA cleared via K213686 on August 12, 2022.

Table 1: Technological Characteristics Comparison

	Subject Device SKOUT System	Predicate Device SKOUT System (K213686)
Intended Use	A gastrointestinal lesion software detection system is a computer-assisted detection device used in conjunction with endoscopy for 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.	Same - A gastrointestinal lesion software detection system is a computer-assisted detection device used in conjunction with endoscopy for 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	Same - 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

	Subject Device SKOUT System	Predicate Device SKOUT System (K213686)
	interpretation of endoscopic procedures, medical diagnosis, or recommendations of treatment/course of action for patients. SKOUT is indicated for white light colonoscopy only.	interpretation of endoscopic procedures, medical diagnosis, or recommendations of treatment/course of action for patients. SKOUT is indicated for white light colonoscopy only.
User Population	Adult patients undergoing colorectal cancer screening or surveillance colonoscopy.	Same - Adult patients undergoing colorectal cancer screening or surveillance colonoscopy.
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.	Similar - The SKOUT system is composed of a multi piece hardware design and software designed to highlight portions of the colon where the device detects potential colorectal polyps.
Software Algorithm	The SKOUT system utilizes an artificial intelligence-based algorithm to perform the polyp detection function.	Same - The SKOUT system utilizes an artificial intelligence-based algorithm to perform the polyp detection function.
Power Source	Hospital mains power	Same - Hospital mains power
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, the subject device 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.	Similar - The Video Display Switch allows for instantaneous toggling between the SKOUT video feed and the standard 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, a green square, located in the top left corner of the SKOUT video feed. This GUI feature is an additional check to the user that the SKOUT system is on and in use, even when polyp detection notifications are not on the screen to prevent undesired use of the AI.

	Subject Device SKOUT System	Predicate Device SKOUT System (K213686)
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.	Same - 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.
Compatible Endoscopes	Olympus EVIS EXERA III and FUJI EC760 series	Same - Olympus EVIS EXERA III and FUJI EC760 series
Video Delay	Assessment of video delay due to marker annotation; SDI 0.0ms (error 1.1ms) Assessment of video delay due to device; SDI 0.0ms (error 1.1ms) Subject device does not have DVI input.	Similar - Assessment of video delay due to marker annotation; 56.00ms (95% CI: 50.54, 61.46) and 3.25 (95% CI: 2.93, 3.56) frame delay for Serial Digital Interface (SDI) and 62.33ms (95% CI: 60.76, 63.90) and 3.74 (95% CI: 3.65, 3.83) frame delay for Digital Visual Interface (DVI). Assessment of real-time endoscopic video delay due to the device; 56.67ms (95% CI: 51.01, 62.33) and 3.28 (95% CI: 2.96, 3.62) frame delay for SDI and 60.67ms (95% CI: 57.72, 63.61) and 3.64 (95% CI: 3.46, 3.81) frame delay for DVI.
Pixel Level Degradation	No pixel level degradation is introduced by SKOUT to the Endoscopic System.	Similar - No visually detectable differences between images were found with the introduction of the SKOUT system.@

The hardware and software differences to the subject device that result in improved performance, these differences do not introduce new questions of safety or effectiveness.

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 design and software do not affect its safety and effectiveness when used as labeled. The algorithm between the two devices remains the same, therefore clinical performance remains unchanged. Performance data demonstrates that the SKOUT system is as safe and effective as the predicate device. Thus, the SKOUT system can be considered substantially equivalent.