August 12, 2022

Iterative Scopes Inc.
Dennis Francoeur
Director of Regulatory Affairs
14 Arrow St, 3rd Floor
Cambridge, MA 02138

Re: K213686
Trade/Device Name: SKOUT Software
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP
Dated: November 22, 2021
Received: November 22, 2021

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, 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)*
K213686

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

Submitter:

Iterative Scopes, Inc.

14 Arrow St, 3rd Floor

Cambridge MA 02138

Phone: (603) 819-8387

Contact Person: Dennis Francoeur, Director of Regulatory Affairs

Date Prepared: August 11, 2022

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: GI Genius, Cosmo Artificial Intelligence - AI, LTD, DEN200055

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. Display of this notification is deactivated if / when a surgical tool enters the frame or if the polyp is no longer being detected.

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). The device status indicator signal displays as a two-dimensional solid green box in the left-hand corner of the display if the device is powered on and actively processing the input video and as a red X if there is a video processing error.

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

Both the subject and the predicate devices are Computer-Assisted Detection (CADe) devices used in conjunction with endoscopy for the detection of abnormal lesions in the gastrointestinal tract. At a high level, the subject and predicate devices are based on the following same technological elements. A table comparing the key features of the subject and predicate devices is provided below:

Table 1: Technological Characteristics Comparison

	SKOUT™ System	**GI Genius**
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.	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 may contain hardware 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	The GI Genius System is a computer-assisted reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard white -light

	SKOUT™ System	GI Genius
	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.	endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. The GI Genius computer-assisted detection device is limited for use with standard white light endoscopy imaging only. This device is not intended to replace clinical decision making.
User Population	Adult patients undergoing colorectal cancer screening or surveillance colonoscopy.	Adult patients undergoing screening and surveillance endoscopic mucosal evaluations.
Technological Characteristics	The SKOUT™ system is composed of hardware and software designed to highlight portions of the colon where the device detects potential colorectal polyps.	The GI Genius is composed of hardware and software designed to highlight portions of the colon where the device detects a potential lesion.
Software Algorithm	The SKOUT™ system utilizes an artificial intelligence-based algorithm to perform the polyp detection function.	The GI Genius system utilizes an artificial intelligence-based algorithm to perform the polyp detection function.
Power Source	Hospital mains power	Hospital mains power
Safety Features	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.	Unknown

	SKOUT™ System	GI Genius
	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 provide a 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.	
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.	During a colonoscopy, the GI Genius system generates markers, which look like green squares and are accompanied by a short, low-volume sound, and superimposes them on the video from the endoscope camera when it identifies a potential lesion.

The SKOUT™ system and GI Genius have the same intended use, similar indications for use, comparable user population, hardware and software characteristics. Both devices provide as an output polyp detection markers that are superimposed onto endoscopic videos. Though there are minor differences between the two devices, such as the Video Display Switch and the low-volume sound, these differences do not raise different questions of safety and effectiveness as demonstrated by the non-clinical and clinical performance evaluation results.

Performance Data

The following testing was conducted for the SKOUT™ system with data included in the 510(k) document.

Software Verification and Validation

Software verification and validation was conducted for the SKOUT™ 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 unit, integration, and requirements 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

Non-clinical performance testing

The following non-clinical performance testing areas, and corresponding results, were conducted:

- Standalone algorithm performance testing; The Standalone Performance Assessment was performed to assess trends in the detection and classification of the SKOUT™ system and determine its ability to discriminate between normal mucosa and polyp tissue. This includes analysis of a predefined set of 79 HD videos with 94 polyps of relevant non-clinical performance metrics to evaluate this performance. These metrics comprehensively encompass standalone SKOUT™ system performance in relation to the algorithm's ability to detect and highlight potential polyps with a bounding box on colonoscopy videos. Of the 94 polyps included in this analysis, SKOUT™ detected 92 polyps.

    - Annotation methods:

Annotation was performed by a team of trained annotators who were assessed on their ability to successfully identify and correctly label polyps.

Ground truth was defined as data reviewed and either validated or created by expert gastroenterologists through a process referred to as gastroenterologist review. During gastroenterologist review, experts reviewed and either validated, rejected or created new labels post primary annotation. Gastroenterologist labels serve as the ground truth for frame level True Positive Rate (TPR), False Positive Rate(FPR) and object level TPR, FPR.

    - Primary Endpoints

1. **Object Level TPR:** The proportion of suspected polyps that were detected by the device in the evaluation dataset and confirmed to be polyps using pathology findings. This metric demonstrates object/polyp level performance of the device algorithm.
2. **Object Level FPs:** The number of suspected polyps that the device bounds per procedure which are not confirmed to be polyps by a) resection and b) pathology findings.

    - Secondary Endpoints

1. **Frame Level TPR:** The proportion of all the frames with confirmed polyps in which the device bounds the polyp in the evaluation dataset.
2. **Frame Level FPR:** The proportion of frames in which the device bounds an object that is not detected by the gastroenterologist in a colonoscopy during normal use (does not include frames when a surgical tool or NBI is detected).

- Demographics

Table 2: Demographic and Baseline Information

Demographics (Total no. of videos = 79)		
Sex		**No. of Videos**
	Male	34
	Female	45
Race		
	White	72
	Asian	3
	Black or African American	2
	Not Reported - Declined	2
Ethnicity		
	Hispanic or Latino Heritage	0
	Non-Hispanic or Latin Heritage	78
	Declined	1
Endoscopic Processor		
	EVIS EXERA III processor CV-190	79

- Results

Table 3: Primary and Secondary Endpoints Results

Object Level True Positive Rate (TPR)	97.87 (95% CI: 94.96, 100.0)
Object Level False Positive (FP)	22.55 objects per a 15 minute interval (95% CI: 18.954, 26.148)
Frame level performance	**(79 videos / 94 polyps)** True positive: 193,861 True negative: 3,459,211 False positive: 81,930 False negative: 154,429
True positive rate per frame	Mean: 55.66 % (95% CI: 55.50, 55.83)
False positive rate per frame	Mean: 2.31% (95% CI:2.16 - 2.44)

- Subgroup analysis of endpoints

Table 4: Subgroups analysis of endpoints

Total Videos = 79, Total Polyps = 94, Total Detected Polyps = 92

		Polyps Detected	Total Polyps	Object TPR	95 % Confidence Interval for Object TPR [low, high]	mean Object FP (15 min interval)	95 % Confidence Interval for mean Object FP (15-min interval) [low, high]
Sex							
	Male	45	46	97.83%	[93.61, 100.0]	25.66	[19.387, 31.927]
	Female	47	48	97.92%	[93.88, 100.0]	20.2	[15.934, 24.4746]
Age							
	40 years to 64 years	60	61	98.36%	[95.17, 100.0]	21.54	[17.002, 26.081]
	65 years and up	32	33	96.97%	[91.12, 100.0]	24.61	[18.429, 30.788]
Size(mm)							
	0 - 4	35	36	98.11%	[94.45, 100.0]	N/A	N/A
	5 - 9	47	48	98.13%	[95.09, 100.0]	N/A	N/A
	10+	10	10	100.00%	[100.0, 100.0]	N/A	N/A
Histology							
	Adenoma	50	50	100.00%	[100.0, 100.0]	N/A	N/A
	SSLs	16	16	100.00%	[100.0, 100.0]	N/A	N/A
	Hyperplastic Polyp	16	17	96.43%	[89.55, 100.0]	N/A	N/A
	Inflammatory Polyp	2	2	100.00%	[100.0, 100.0]	N/A	N/A
	Not Histologically a Polyp	5	6	90.91%	[79.79, 100.0]	N/A	N/A
	Unknown	3	3	100.00%	[100.0, 100.0]	N/A	N/A
Race							

	Declined	2	2	100.00%	[100.0, 100.0]	37.72	[30.512, 47.189]
	White	78	80	97.50%	[94.08, 100.0]	21.91	[18.364, 25.46]
	Asian	11	11	100.00%	[100.0, 100.0]	34.69	[9.012, 78.4]
	Black or African American	1	1	100.00%	[100.0, 100.0]	12.18	[5.269, 19.622]

- Marker Persistence is defined as the continuous uninterrupted detection of a target in time. Alternatively, it can be explained as the time (in milliseconds) from the first appearance of a marker on a polyp until the first disappearance of the marker for the same polyp.

  A sensitivity analysis of marker persistence is performed with all 79 videos denoting the object-level True Positive Rate and False Positive event count (mean per 15 minute session) as a function of marker persistence.

  The following graph demonstrates that markers with higher persistence have a higher likelihood to be true positives.

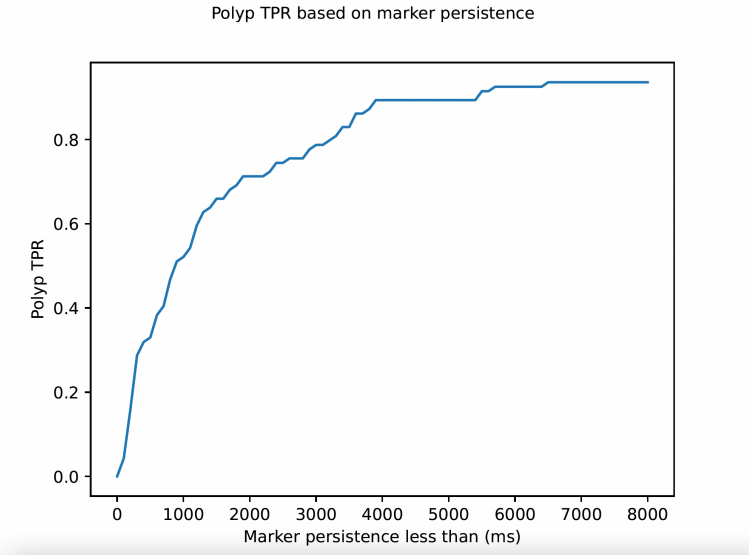

Figure 1: Polyp TPR based on Marker Persistence

The plot below shows FP events (per 15 min) as a function of marker persistence. The graph demonstrates that the majority of FP events occur with markers that persist for 1 second or less.

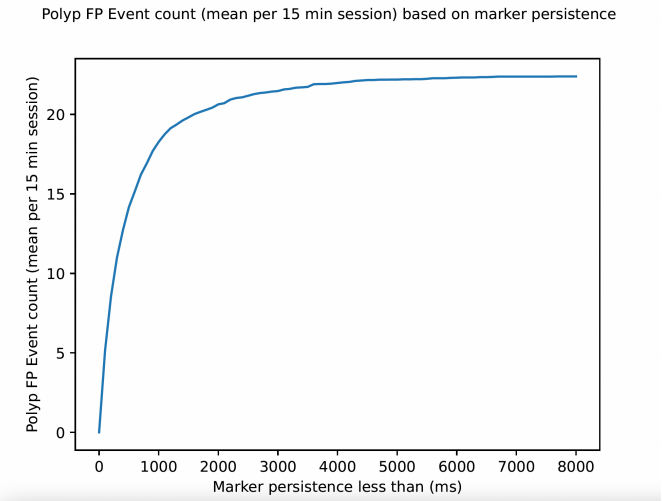

Figure 2: Polyp FP Event count (mean per 15 min session) based on Marker Persistence

- Marker Overlap: In order to not obstruct gastroenterologists' view of polyps, SKOUT™ artificially increases the size of the boxes output by its AI algorithm.

  Various metrics are used to understand SKOUT™'s overlap performance with the ground truth reference standards.

  Intersection over Union (IOU) is the ratio of area of intersection of the SKOUT™ signal with just the intersection of the two boxes over the total area of both boxes (Figure 03). This calculation means that when comparing SKOUT's performance (artificially increased bounding box), the IOU figure should be low.

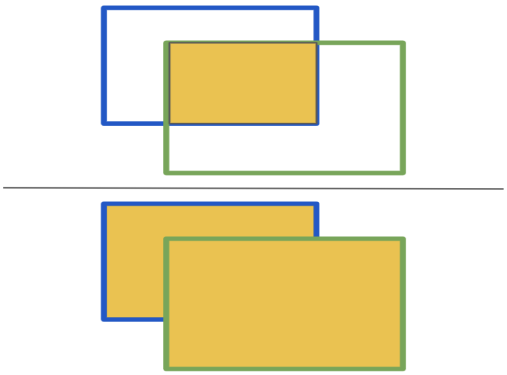

Figure 03: IOU

Intersection over Ground Truth (IOGT) is the ratio of area of intersection of SKOUT™ signal with ground truth bounding box over the area of the ground truth box (Figure 04). An IOGT value of 1 indicates that the ground truth box is fully

engulfed by the SKOUT™ signal.

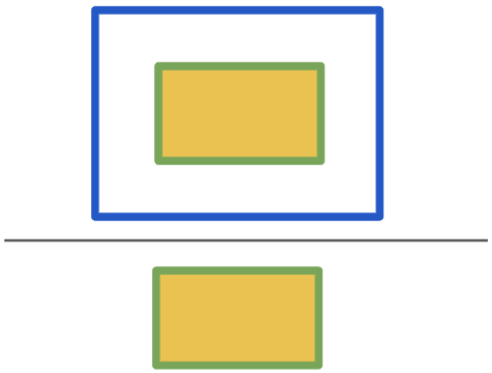

Figure 04: IOGT

Our results show that our IOU was 0.299. More importantly, our IOGT value was 1.0 which indicates that on a median basis, all polyps were engulfed by a SKOUT bounding box.

Table 05: Signal overlap analysis

Mean, 95% confidence interval if IOU of signal on 411 samples	0.299, [0.289, 0.309]
Median IOGT of signal	1.0

- Special Control Testing
  - Pixel-level comparison of degradation of image quality due to the device; No visually detectable differences between images were found with the introduction of the SKOUT™ system.
  - 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.

Human Factors

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.

Clinical Testing

A multicenter, prospective, randomized controlled trial of the SKOUT™ system was conducted in the United States in order to evaluate the safety and efficacy of this device. The study design involved 2 arms in which adult patients undergoing either screening or surveillance colonoscopy procedures were randomized to either an AI-aided arm (standard colonoscopy with the use of the SKOUT™ system), or the control arm (standard colonoscopy without the use of the SKOUT™ system).

The aim of this study is to evaluate the clinical benefit and safety of using a computer-aided detection (CADe) device, the SKOUT™ system, in colonoscopy procedures with the indication of screening or surveillance.

Inclusion Criteria:

- Undergoing colonoscopy with screening or surveillance.
- Whose endoscopist is a participating provider.
- Who have given informed consent.

Exclusion Criteria:

- Have a history of inflammatory bowel disease.
- Have a history of familial adenomatous polyposis.
- Are under the age of 40.
- Have had a colonoscopy within the previous three (3) years.
- Patients undergoing diagnostic colonoscopy with high risk indications including iron deficiency anemia, abnormal CT imaging, unexplained weight loss, Lynch Syndrome, blood in stool or FIT positive test.
- Use anti-platelet agents or anticoagulants that preclude the removal of polyps during the procedure.
- Entered with poor bowel preparation (inadequate for procedure as assessed by the Investigator).

Provider's Eligibility requirements:

- United States board-certified gastroenterologist.
- Has performed at least 1,000 colonoscopies.
- Has an ADR greater than or equal to 25%.

The co-primary endpoints of the study included a performance endpoint (adenomas per colonoscopy - APC) and a safety endpoint (positive percent agreement – PPA).

- APC: The total number of adenomas detected divided by the total number of colonoscopies.
- PPA**: PPA is the fraction of adenomas, sessile serrated lesions, and hyperplastic polyps of the proximal colon (caecum, ascending colon, hepatic flexure, and transverse colon) out of the total number of resections.
- PPA (or PPV): It is the fraction of adenomas, sessile serrated lesions, and large (>10mm) hyperplastic polyps of the proximal colon (caecum, ascending colon, hepatic flexure, and transverse colon) out of total number of resections.

Table 06:Demographics and Baseline Information

	Control (N=677)	Treatment (N=682)	p-value
Sex			0.612
Male	355 (52.4%)	368 (54%)	
Female	322 (47.6%)	314 (46%)	
Age - Continuous			0.159
Mean (SD)	59.9 (8.8)	60.6 (8.9)	
Age - Categorical			0.21
40 <= years < 50	54 (8%)	53 (7.8%)	
50 <= years < 65	415 (61.3%)	389 (57%)	
>= 65 years	208 (30.7%)	240 (35.2%)	
Race			0.194*
American Indian or Alaska Native	2 (0.3%)	0 (0%)	
Asian	21 (3.1%)	18 (2.6%)	
Black or African American	36 (5.3%)	47 (6.9%)	
Native Hawaiian or Other Pacific-Islander	3 (0.4%)	0 (0%)	
White	563 (83.2%)	567 (83.3%)	
More Than One Race	5 (0.7%)	2 (0.3%)	
Don't Know	11 (1.6%)	18 (2.6%)	
Refused	36 (5.3%)	29 (4.3%)	
Ethnicity			0.596
Not Hispanic or Latino	627 (92.6%)	627 (91.9%)	
Hispanic or Latino	31 (4.6%)	29 (4.3%)	
Don't Know	7 (1%)	13 (1.9%)	
Refused	12 (1.8%)	13 (1.9%)	
Site of Procedure			>0.99
Concord Endoscopy Center	206 (30.4%)	210 (30.8%)	
Mount Auburn Hospital	168 (24.8%)	163 (23.9%)	
Massachusetts General Hospital	59 (8.7%)	62 (9.1%)	
MNGI Digestive Health	160 (23.6%)	161 (23.6%)	
Boston Medical Center	84 (12.4%)	86 (12.6%)	
Years Since Last Colonscopy			>0.99
3 <= years < 5	71 (10.5%)	72 (10.6%)	
5 <= years < 10	261 (38.6%)	268 (39.3%)	
>= 10 years	129 (19.1%)	127 (18.6%)	
No Previous Colonoscopy	216 (31.9%)	215 (31.5%)	

* Fisher's Exact Test Used Instead of Chi-Square Test

A total of 1,359 patients were included in the modified Intention To Treat (mITT) population for primary analysis, including 682 who received a colonoscopy with the SKOUT™ system and 677 who received a standard colonoscopy. The evaluation of our primary endpoints and secondary endpoint for the mITT population is summarized below:

Table 07: Primary and Secondary Endpoints results for mITT population

	Control (N=677)	Treatment (N=682)	Difference (Treatment-Control)	95% CI for Difference	p-value
Adenomas Per Colonoscopy*	0.830	1.054	0.224	(0.060, 0.382)	0.002
Positive Predictive Value	0.717	0.674	-0.043	(-0.094, 0.010)	<0.001
Adenoma Detection Rate*	0.439	0.478	0.039	(-0.012, 0.097)	0.065
Average Number of Sessile Serrated Lesions	0.284	0.199	-0.084	(0.003, 0.165)	0.042
Mean Surveillance Interval for Next Colonoscopy	6.307	6.275	-0.032	(-0.275, 0.338)	0.839

APC and PPV are Co-Primary Endpoints
* No Adenocarcinomas Found

In the mITT cohort, PPA** was found to be 75.7% in the control arm (n=677) and 70.9% in the treatment arm (n=682), a difference of -4.8%. The 95% CI for the difference is (- 9.5% to 0.3%) and the p-value is <0.001.

No adverse events or complications were reported during the study.

Table 08: Polyp Characteristics and Baseline Information

	Standard (N=1129)	Skout Colonoscopy (N=1334)	P value
Polyp Location (Endoscopy Report)			0.641
Rectum	116 (10.7%)	141 (10.9%)	
Rectosigmoid	27 (2.5%)	39 (3%)	
Sigmoid	169 (15.6%)	193 (14.9%)	
Descending Colon	111 (10.2%)	132 (10.2%)	
Splenic Flexure	12 (1.1%)	18 (1.4%)	
Transverse Colon	270 (24.9%)	293 (22.6%)	
Hepatic Flexure	41 (3.8%)	69 (5.3%)	
Ascending Colon	250 (23%)	295 (22.7%)	
Cecum	90 (8.3%)	119 (9.2%)	
Polyp Size (Via Endoscopy Report)			0.125
Mean (SD)	5 (3)	4.8 (3.1)	
Polyp Size (via Endoscopy Report)			<0.001*
<5 mm	607 (53.8%)	720 (54%)	
5 <= mm < 10	410 (36.3%)	537 (40.3%)	
>= 10 mm	112 (9.9%)	77 (5.8%)	
Size Unmatched	0 (0%)	0 (0%)	
Polyp Morphology			0.185
Sessile	937 (86.4%)	1123 (86.6%)	
Pedunculated	87 (8%)	82 (6.3%)	
Flat	48 (4.4%)	76 (5.9%)	
Not Available	12 (1.1%)	16 (1.2%)	
Polyp Histology			<0.001*
Hyperplastic	205 (18.9%)	280 (21.6%)	
Adenoma	557 (51.4%)	716 (55.2%)	
Adenoma with High-Grade Dysplasia	2 (0.2%)	2 (0.2%)	
Tubulovillous Adenoma	22 (2%)	30 (2.3%)	
Tubulovillous Adenoma with High-Grade Dysplasia	3 (0.3%)	0 (0%)	
Villous Adenoma	0 (0%)	0 (0%)	
Villous Adenoma with High-Grade Dysplasia	0 (0%)	0 (0%)	
Sessile Serrated Adenoma	188 (17.3%)	141 (10.9%)	
Sessile Serrated Adenoma with High-Grade Dysplasia	0 (0%)	0 (0%)	
Traditional Serrated Adenoma	8 (0.7%)	0 (0%)	
Traditional Serrated Adenoma with High-Grade Dysplasia	0 (0%)	0 (0%)	
Adenocarinoma	0 (0%)	0 (0%)	
Carninoid Tumor	0 (0%)	0 (0%)	
Inflammatory Polyp	9 (0.8%)	16 (1.2%)	
Unknown/Unavailable	12 (1.1%)	16 (1.2%)	
Not Histologically A Polyp	78 (7.2%)	96 (7.4%)	
Polyp Match			0.007
One-to-One Match	892 (81.8%)	1118 (85.9%)	
Match Cannot Be Determined	199 (18.2%)	183 (14.1%)	

Table 09: Relationship between size of resected polyps and their location

	Standard (N=1129)	Skout Colonoscopy (N=1334)	P value
Distal Colon			0.282
Mean (SD)	4.8 (2.7)	4.6 (2.7)	
Distal Colon			0.1*
<5 mm	234 (53.8%)	308 (58.9%)	
5 <= mm < 10	170 (39.1%)	192 (36.7%)	
>= 10 mm	31 (7.1%)	23 (4.4%)	
Size Unmatched	0 (0%)	0 (0%)	
Proximal Colon			0.27
Mean (SD)	5.2 (3.2)	5 (3.2)	
Proximal Colon			<0.001*
<5 mm	346 (53.1%)	389 (50.1%)	
5 <= mm < 10	230 (35.3%)	335 (43.2%)	
>= 10 mm	75 (11.5%)	52 (6.7%)	
Size Unmatched	0 (0%)	0 (0%)	

Table 10: Relationship between size of resected polyps across histology:

	Control (N=986)	Treatment (N=1168)	p-value
Adenoma			
Size: < 5 mm	301 (30.527%)	376 (32.192%)	0.434
Size: 5 <= mm < 10	221 (22.414%)	327 (27.997%)	0.004
Size: >= 10 mm	63 (6.389%)	44 (3.767%)	0.007
Size: All Sizes	585 (59.331%)	747 (63.955%)	0.031
SSL			
Size: < 5 mm	70 (7.099%)	36 (3.082%)	<0.001
Size: 5 <= mm < 10	90 (9.128%)	79 (6.764%)	0.051
Size: >= 10 mm	36 (3.651%)	26 (2.226%)	0.066
Size: All Sizes	196 (19.878%)	141 (12.072%)	<0.001
Hyperplastic			
Size: < 5 mm	138 (13.996%)	200 (17.123%)	0.054
Size: 5 <= mm < 10	64 (6.491%)	77 (6.592%)	>0.99
Size: >= 10 mm	3 (0.304%)	3 (0.257%)	>0.99
Size: All Sizes	205 (20.791%)	280 (23.973%)	0.087

The results of the clinical performance as documented in the pivotal clinical study show a statistically significant increase in APC, and PPA fell statistically within the prespecified noninferiority margin , demonstrating that the performance of the SKOUT™ system achieved benchmark expectations and a safety and effectiveness profile comparable to the predicate device.

Conclusions

The SKOUT™ system has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the SKOUT™ system and its predicate device do not raise different issues of safety or effectiveness. Performance data from this study demonstrate that the SKOUT™ system is as safe and effective as the predicate device. Thus, the SKOUT™ system can be considered substantially equivalent.