August 5, 2026

Xiamen Inno Medical Technology Co.,Ltd.
℅ Rachel Yu
Regulatory Manager
ZHIHE Info-Tech(Suzhou) Co., Ltd.
Room 616, Building 1, No. 1 Huayun Road, Industrial Park
Suzhou, Jiangsu 215134
China

Re: K252853
Trade/Device Name: CAD - Lower GI (EC07-01)
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP
Dated: July 4, 2026
Received: July 6, 2026

Dear Rachel Yu:

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,

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

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.	K252853

Please provide the device trade name(s).

CAD - Lower GI

Please provide your Indications for Use below.

CAD - Lower GI is a computer-assisted reading tool intended to aid qualified endoscopists in detecting suspected colonic mucosal lesions, such as polyps and adenomas, in real-time endoscopic images obtained during colorectal endoscopy.
The device is intended for use in adult patients undergoing colorectal cancer screening or surveillance colonoscopy in medical institutions.
The device detects and displays areas of suspected lesions to assist endoscopists during colorectal endoscopy. The device is not intended to characterize lesions or replace clinical judgment. Physicians shall evaluate the device output together with the endoscopic images and other clinical information and shall not make clinical decisions solely based on the device output.
The product is intended to be used only with specified compatible image processors and video endoscopes under white light and NBI modes.

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

I Submitter

Device Submitter： Xiamen Inno Medical Technology Co., Ltd.
Unit 203-2, No. 55, Chengyi North Street, Phase 3 of software park, Xiamen, Fujian Province, China

Contact Person: Jianqing Zhao
Title: Manager
Phone: +86 173 5002 8269
Email: zhaojq@xm-innovision.com

Date Prepared: September 5, 2025

II Device

Trade Name of Device: CAD - Lower GI
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulation Class: II
Product code: QNP
Review Panel: Gastroenterology/Urology

III Predicate Device 1

Trade/Device Name:	GI Genius™ Module 100 (GGM100.US); GI Genius™ Module 200 (GGM200.US); ColonPRO™ 4.0 (CPRO40.US)
Regulation Number:	21 CFR 876.1520
Regulation Name:	Gastrointestinal Lesion Software Detection System
Regulatory Class:	Class II
Product Code:	QNP
Premarket Notification:	K233964
Manufacturer:	Cosmo Artificial Intelligence - AI Ltd

IV Predicate Device 2

Trade/Device Name:	GI Genius
Regulation Number:	21 CFR 876.1520
Regulation Name:	Gastrointestinal Lesion Software Detection System
Regulatory Class:	Class II
Product Code:	QNP
Submission Number:	DEN200055
Manufacturer:	Cosmo Artificial Intelligence - AI, LTD

V Device Description

CAD-Lower GI is an artificial intelligence-based standalone medical device software designed to process colonoscopy images and assist in the real-time detection of suspected colorectal polyps during procedures in adult patients. It is intended to aid physicians in medical institutions and is not meant to replace full patient evaluation or confirm diagnoses.

The device is delivered as a software installation package via email, comprising modules for colorectal polyp detection, video display, recording, system settings, and user management. The polyp detection module uses a deep learning algorithm to analyze endoscopic images and highlight suspected polyp locations in real-time.

CAD-Lower GI is compatible with endoscopic image processors (CV-190 and CV-1500, Olympus Medical Corporation) and their compatible video colorectal endoscopes, supporting white light(WLI) and Narrow Band Imaging (NBI) modes. It connects between the processor's SDI-OUT (HD-SDI/3G-SDI) and a computer system's video capture card, outputting processed images to a monitor via DP-OUT to DVI-IN/DP-IN.

The software operates on a user-provided computer system running Ubuntu 22.04 LTS, requiring an Intel i7-7700k or higher CPU, ≥16 GB memory, NVIDIA RTX 3070 or higher graphics card, a video capture card supporting 1080I@50Hz or 1080P@60Hz with ≥400 MB/s bandwidth, and a 1920x1080 resolution monitor. An Ethernet connection (RJ45, ≥100 Mbps) with a firewall is needed for license activation.

During colonoscopy, CAD-Lower GI processes live video streams, overlaying colored box markers on the display monitor to highlight suspected polyps in real-time, without altering the original video feed. It supports standard endoscopic workflows, enhancing physician awareness through AI-driven image analysis.

VI Indications for Use

CAD - Lower GI is a computer-assisted reading tool intended to aid qualified endoscopists in detecting suspected colonic mucosal lesions, such as polyps and adenomas, in real-time endoscopic images obtained during colorectal endoscopy.

The device is intended for use in adult patients undergoing colorectal cancer screening or surveillance colonoscopy in medical institutions.

The device detects and displays areas of suspected lesions to assist endoscopists during colorectal endoscopy. The device is not intended to characterize lesions or replace clinical judgment. Physicians shall evaluate the device output together with the endoscopic images and other clinical information and shall not make clinical decisions solely based on the device output.

The product is intended to be used only with specified compatible image processors and video endoscopes under white light and NBI modes.

VII Substantial Equivalence Discussion

The comparison and discussion between the subject device and the predicate devices are listed in below tables:

Table 1: Comparison of CAD - Lower GI to GI Genius

Items	**Subject Device** CAD - Lower GI	**Predicate Device 1** GI Genius™ Module 100; GI Genius™ Module 200; ColonPRO™ 4.0. (K233964)	**Predicate Device 2** GI Genius (DEN200055)
FDA Reg name	Gastrointestinal lesion software detection system	Gastrointestinal lesion software detection system	Gastrointestinal lesion software detection system
FDA Reg #	21 CFR 876.1520	21 CFR 876.1520	21 CFR 876.1520
Product Code	QNP	QNP	QNP
Indications for Use	CAD - Lower GI is a computer-assisted reading tool intended to aid qualified endoscopists in detecting suspected colonic mucosal lesions, such as polyps and adenomas, in real-time endoscopic images obtained during colorectal endoscopy. The device is intended for use in adult patients undergoing colorectal cancer screening or surveillance colonoscopy in medical institutions. The device detects and displays areas of suspected lesions to assist endoscopists during colorectal endoscopy. The device is not intended to characterize lesions or replace clinical judgment. Physicians shall evaluate the device output together with the endoscopic images and other clinical information and shall not make clinical decisions solely based on the device output. The product is intended to be used only with specified compatible image processors and video endoscopes under white light and NBI modes.	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 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.	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 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.
Video delay, signal in to signal out	The maximum real-time video delay is 30ms	GI Genius™ Module 100 with ColonPRO™ 4.0: 1.52 µs GI Genius™ Module 200 with ColonPRO™ 4.0: 0.74 µs	1.52 µs
Annotation delay	The maximum annotation delay is 38ms	Time is less than or equal to 120 milliseconds	Time is less than or equal to 120 milliseconds
Video quality integrity test	The maximum color error of image quality degradation caused by device is 0.777427, which is only slightly recognizable to human eyes	There should be no degradation in image quality, meaning that all corresponding pixels (from the endoscopic video processor and from the GI Genius) are identical in the three color channels	There should be no degradation in image quality, meaning that all corresponding pixels (from the endoscopic video processor and from the GI Genius) are identical in the

Items	Subject Device CAD - Lower GI	Predicate Device 1 GI Genius™ Module 100; GI Genius™ Module 200; ColonPRO™ 4.0. (K233964)	Predicate Device 2 GI Genius (DEN200055)
			three color channels
Video processor	Olympus CV-190, Olympus CV-1500	Olympus CV-180, Olympus CV-190, Pentax EPK-i7000, Fujifilm VP-4450HD Fujifilm VP-7000 Olympus CV-1500	Olympus CV-180, Olympus CV-190, Pentax EPK-i7000, Fujifilm VP-4450HD
Accessories (optional)	None	Footswitch USB K-switch	N/A
Software other function	Recording and file management function	Procedure Highlights function	N/A
Electrical safety	The CAD - Lower GI is a standalone SaMD (Software as a Medical Device) without hardware.	IEC 60601-1	IEC 60601-1
Electromagnetic compatibility	The CAD - Lower GI is a standalone SaMD (Software as a Medical Device) without hardware.	IEC 60601-1-2	IEC 60601-1-2
LAN port	Yes, non-functional to user	Yes, non-functional to user	No

CAD - Lower GI has the same intended use and similar technological characteristics as the predicate devices. The identified differences, including support for NBI imaging and differences in video-processing architecture, were evaluated through nonclinical and clinical performance testing. These differences do not raise different questions of safety or effectiveness and do not affect the substantial equivalence determination.

VIII Non-Clinical Tests

The following non-clinical verification and validation activities have been completed for the CAD – Lower GI device:

- System-level software verification was conducted against the Software Requirements Specification (SRS). All specified requirements were tested and met, covering multiple functional units and items.
- User-level software validation was performed in accordance with the SRS, confirming that the device performs as intended in its clinical context of use.
- Risk control measures identified during the risk management process were verified or validated, as appropriate, to ensure risk mitigations are effective.
- Standalone performance testing was conducted, including evaluation on static image datasets, dynamic video datasets, and public third-party clinical research data. Key parameters assessed included lesion-based sensitivity, true positive and false positive rates per frame, ROC curve (AUC), and false positive clusters per patient. Results demonstrated performance within or exceeding the range of predicate devices.
- Video processing tests verified signal acquisition, annotation latency (≤40 ms), and frame synchronization.
- Cybersecurity measures related to Ethernet communication with the User Activation Management Platform were implemented and assessed in accordance with FDA guidance documents (*Cybersecurity in Medical*

Devices: Quality System Considerations and Content of Premarket Submissions).

The results of these activities demonstrate that the CAD – Lower GI meets its specifications and support a finding of substantial equivalence to the predicate devices.

Performance Data

The following testing was conducted for the CAD - Lower GI system with data included in the 510(k) document.

- **Software Verification and Validation**

The Software verification and validation was conducted for the CAD - Lower GI 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 CAD - Lower GI software demonstrated passing results on all applicable unit, integration, and requirements testing.

- **Standalone Performance Testing**

The purpose of the standalone performance testing is to demonstrate that overall algorithmic performance is sufficient to fulfill the indications for use of the CAD - Lower GI. The standalone performance evaluation was carried out using the static image datasets, dynamic video datasets, and public third-party data which are shown in Tables 2-8. The Static Image Dataset is used exclusively as an internal validation dataset. The public third-party data sourced from open-source dataset REAL-Colon. This evaluation was performed in both WLI and NBI modes.

Table 2: Detailed Static Image Dataset

Items	Classification Criteria	Number of Images			Total
		Positive	Negative	Total	
Age	<45	9405	10433	19838	58464
	≥45	21382	17244	38626	
Gender	Male	17254	15522	32776	58464
	Female	13533	12155	25688	
Image Processor	Olympus CV-1500	6699	5571	12270	12270
Light Source	WLI	25594	26222	51816	58464
	NBI	5193	1455	6648	
Lesion Nature	Inflammatory/Hyperplastic Polyp	17227	-	17227	31185
	Adenoma	13958	-	13958	
Lesion Morphology	Yamada Type I	15944	-	15944	31504
	Yamada Type II	12677	-	12677	
	Yamada Type III	2399	-	2399	
	Yamada Type IV	484	-	484	

Table 3: Detailed Image-Based Dynamic Video Dataset

Items	Classification Criteria	Number of Images			Total
		Positive	Negative	Total	
Age	<45	243134	2021403	2264537	5161320
	≥45	284219	2612564	2896783	
Gender	Female	242005	2016984	2258989	5161320
	Male	285348	2616983	2902331	
Image Processor	Olympus CV-1500	150337	1676445	1826782	2876012
	Olympus CV-190	129204	920026	1049230	
Light Source	WLI	423252	4487397	4910649	5161320
	NBI	104101	146570	250671	
Lesion	Inflammatory/Hyperplastic	322869	-	322869	

Nature	Polyp				528766
	Adenoma	205897	-	205897	
Lesion Morphology	Yamada Type I	397935	-	397935	528545
	Yamada Type II	92928	-	92928	
	Yamada Type III	35386	-	35386	
	Yamada Type IV	2296	-	2296	

Table 4: Detailed Lesion-Based Dynamic Video Dataset

Item	Classification Criteria	Number of Positive Lesions	Total
Age	<45	265	507
	≥45	242	
Gender	Male	273	507
	Female	234	
Image Processor	Olympus CV-1500	130	246
	Olympus CV-190	116	
Light Source	WLI	496	725
	NBI	229	
Lesion Nature	Inflammatory/Hyperplastic Polyp	377	507
	Adenoma	130	
Lesion Morphology	Yamada Type I	442	507
	Yamada Type II	53	
	Yamada Type III	10	
	Yamada Type IV	2	

Table 5: Detailed Case-Based Dynamic Video Dataset

Items	Classification Criteria	Number of Cases			Total
		Positive Cases	Negative Cases	Total Cases	
Age	<45	94	2	96	209
	≥45	106	7	113	
Gender	Male	107	3	110	209
	Female	93	6	99	
Image Processor	Olympus CV-1500	46	9	55	104
	Olympus CV-190	49	0	49	

Table 6: Detailed Image-Based Third-party Data

Items	Classification Criteria	Number of Images			Total
		Positive	Negative	Total	
Age	< 45	3512	44439	47951	2393916
	≥45	206153	2139812	2345965	
Gender	Male	127544	1233158	1360702	2393916
	Female	82121	951093	1033214	
Endoscope Brands	Olympus	195771	2000039	2195810	2393916
	Fujifilm	13894	184212	198106	
Lesion Nature	Hyperplastic/Inflammatory Polyp	112017	-	112017	209833
	Adenoma	97816	-	97816	
Lesion Size	0-5mm	165992	-	165992	209665
	6-9mm	20096	-	20096	

	≥10mm	23577	-	23577	

Table 7: Detailed Lesion-Based Third-party Data

Items	Classification Criteria	Number of Positive Lesions	Total
Age	<45	3	132
	≥45	129	
Gender	Male	79	132
	Female	53	
Endoscope Brands	Olympus	117	132
	Fujifilm	15	
Lesion Nature	Hyperplastic/Inflammatory Polyp	76	132
	Adenoma	56	
Lesion Size	0-5mm	117	132
	6-9mm	12	
	≥10mm	3	

Table 8: Detailed Case-Based Third-party Data

Items	Classification Criteria	Number of Cases			Total
		Positive Cases	Negative Cases	Total Cases	
Age	< 45	1	1	2	60
	≥45	45	13	58	
Gender	Male	27	6	33	60
	Female	19	8	27	
Endoscope Brands	Olympus	42	11	53	60
	Fujifilm	4	3	7	
Region	001	9	6	15	60
	002	11	4	15	
	003	14	1	15	
	004	12	3	15	

*In Table 2, Table 3 and Table 6, since a single positive image may contain multiple positive lesions with different lesion nature, lesion size and lesion morphologies, there are differences in the statistics of lesion nature, lesion morphology and the total number of positives. In Table 4, since a single lesion is counted multiple times under different light sources, the number of light source lesions is different from other subgroup. In Table 8, 001 represents the United States, the United Kingdom, and Italy; 002 represents Italy; 003 represents Austria; 004 represents Japan.

In static image dataset, sensitivity, specificity and precision were calcuated as the evaluation metrics. The evaluation results of static image dataset are show in Table 9 below.

Table 9: Evaluation Results for Static Image Dataset

Items		Sensitivity(%)[95% CI]	Specificity(%)[95% CI]	Precision(%) [95% CI]
Overall		98.68 [98.56-98.81]	98.34 [98.19-98.49]	98.51 [98.38-98.65]
Light Source	WLI	98.68 [98.54-98.82]	98.34 [98.19-98.50]	98.31 [98.15-98.47]
	NBI	98.69 [98.38-99.00]	98.28 [97.61-98.95]	99.51 [99.32-99.70]
Image Processor	Olympus CV-1500	98.52 [98.23-98.81]	96.46 [95.98-96.95]	97.10 [96.70-97.50]

In dynamic video dataset and third-party data, frame level TPR(True Positive Rate) and FPR(False Positive Rate), lesion level TPR and FPs(False Positive clusters) per patient are designed for evaluation metrics. In lesion level TPR, a polyp is considered detected if the CAD - Lower GI bounding box adequately overlaps with the ground truth in at least one frame. The FPs per patient represent the average number of false positives per patient. It specifically refers to false-positive events detected on negative frames that contain no ground-truth(GT) polyps The testing

below considers repeated marking overlays of the same false positives as a single statistical event, instead of considering only markings in individual frames as a single statistical event. The evaluation results of dynamic video dataset and third-party data are shown in Table 10-12.

Table 10: Evaluation Results for Dynamic Video Dataset (IoU=0.5, persistence>0)

Items		**Frame Level TPR(%) [95% CI]**	**Frame Level FPR(%) [95% CI]**	**Lesion Level TPR(%) [95% CI]**	**FPs per patient**
Overall		65.04 [64.91-65.17]	0.84 [0.83-0.84]	100 [100-100]	9.87 [8.97-10.76]
Light Source	WLI	64.34 [64.19-64.48]	0.83 [0.82-0.84]	100 [100-100]	-
	NBI	67.89 [67.61-68.18]	1.03 [0.97-1.08]	100 [100-100]	-
Image Processor	Olympus CV-1500	63.62 [63.38-63.87]	1.16 [1.14-1.18]	100 [100-100]	-
	Olympus CV-190	65.87 [65.61-66.13]	0.7 [0.68-0.72]	100 [100-100]	-
Overall Frame Level Performance		True positive: 342,978 True negative: 4,595,256 False positive: 38,711 False negative: 184,375 (209 videos/ 507 polyps)			

Table 11: Evaluation Results for Third-party Data (IoU=0.1, persistence>0)

Items		**Frame Level TPR(%) [95% CI]**	**Frame Level FPR(%) [95% CI]**	**Lesion Level TPR(%) [95% CI]**	**FPs per patient**
Overall		60.3 [60.09-60.51]	1.77 [1.75-1.79]	100 [100-100]	61.30 [50.12-72.48]
Endoscope Brands	Olympus	60.93 [60.72-61.15]	1.82 [1.80-1.84]	100 [100-100]	-
	Fujifilm	51.41 [50.58-52.24]	1.25 [1.20-1.30]	100 [100-100]	-
Overall Frame Level Performance		True positive:126,429 True negative: 2,145,564 False positive: 38,687 False negative: 83,236 (60 videos/ 132 polyps)			

Figures 1-2 showed ROC curve with confidence as threshold for the dynamic video dataset and the third-party data. The AUC values of ROC curvcs were respectively 0.8715(dynamic video dataset) and 0.8297(third-party data). The results showed that the CAD - Lower GI has high accuracy.

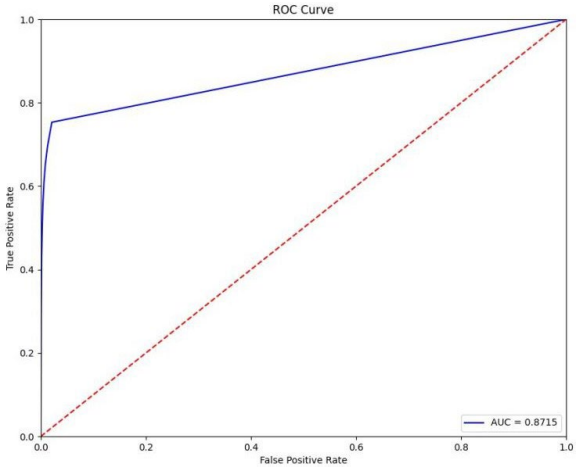

Figure 1: ROC Curve for Dynamic Video Dataset

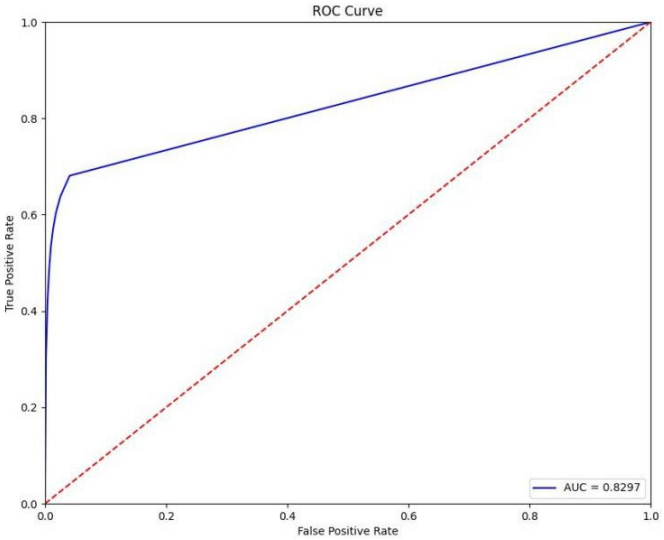

Figure 2: ROC Curve for Third-party Data

Figures 3-4 showed FROC curve with confidence as threshold for the dynamic video dataset and the third-party data.

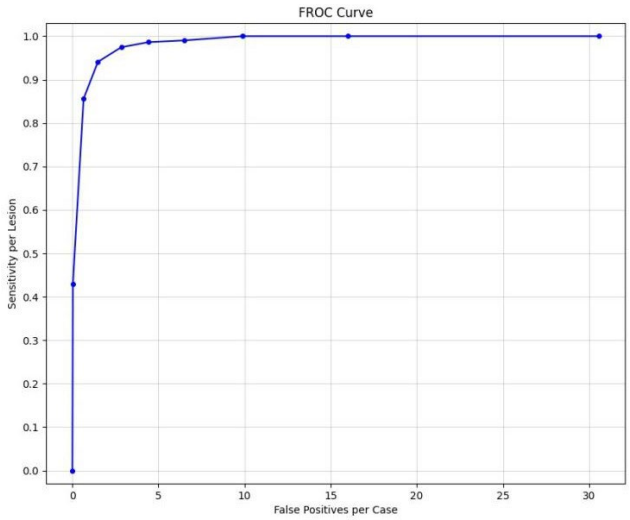

Figure 3: FROC Curve with Confidence as Threshold (dynamic video dataset)

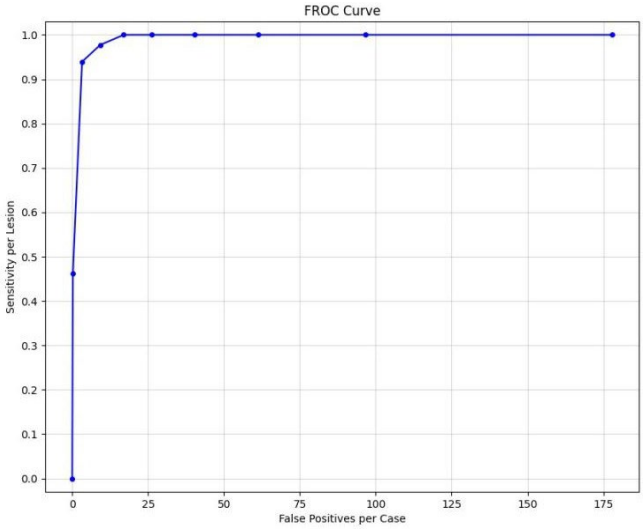

Figure 4: FROC Curve with Confidence as Threshold (third-party data)

Figures 5–6 and Tables 12–13 show the FROC curves and supporting data using IoU as the threshold for the dynamic video dataset and third-party dataset.

The results show that FPC remained unchanged across the evaluated IoU thresholds, while lesion-level sensitivity decreased at higher IoU thresholds due to the more stringent localization criterion.

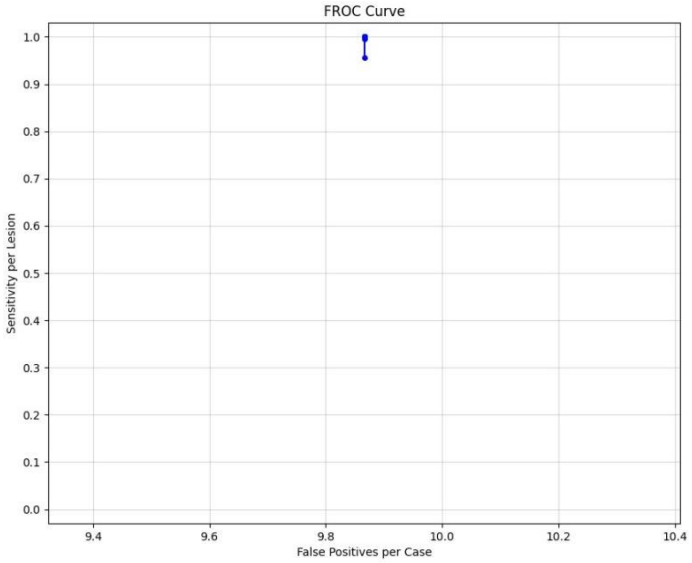

Figure 5: FROC Curve with IoU as Threshold (dynamic video dataset)

Table 12: FROC Data source table with IoU as Threshold (dynamic video dataset)

IoU	FPC	95% CI-L	95% CI-U	Sensitivity per Lesion	95% CI-L	95% CI-U
0.1	9.87	8.97	10.76	100.00%	100.00%	100.00%
0.2	9.87	8.97	10.76	100.00%	100.00%	100.00%
0.3	9.87	8.97	10.76	100.00%	100.00%	100.00%
0.4	9.87	8.97	10.76	100.00%	100.00%	100.00%
0.5	9.87	8.97	10.76	100.00%	100.00%	100.00%
0.6	9.87	8.97	10.76	99.80%	99.42%	100.00%
0.7	9.87	8.97	10.76	99.80%	99.42%	100.00%
0.8	9.87	8.97	10.76	99.61%	99.06%	100.00%
0.9	9.87	8.97	10.76	95.66%	93.89%	97.43%

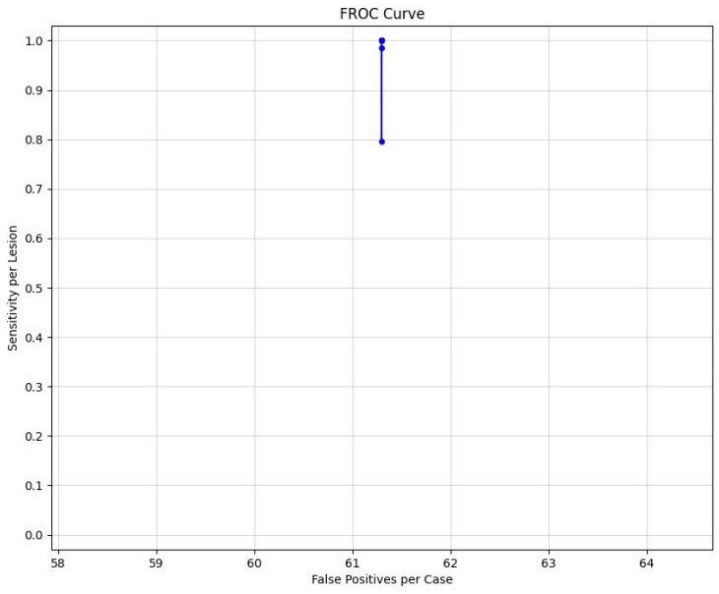

Figure 6: FROC Curve with IoU as Threshold (third-party data)

Table 13: FROC Data source table with IoU as Threshold (third-party data)

IoU	FPC	95% CI-L	95% CI-U	Sensitivity per Lesion	95% CI-L	95% CI-U
0.1	61.30	50.12	72.48	100.00%	100.00%	100.00%
0.2	61.30	50.12	72.48	100.00%	100.00%	100.00%
0.3	61.30	50.12	72.48	100.00%	100.00%	100.00%
0.4	61.30	50.12	72.48	100.00%	100.00%	100.00%
0.5	61.30	50.12	72.48	100.00%	100.00%	100.00%
0.6	61.30	50.12	72.48	100.00%	100.00%	100.00%
0.7	61.30	50.12	72.48	100.00%	100.00%	100.00%
0.8	61.30	50.12	72.48	98.48%	96.40%	100.00%
0.9	61.30	50.12	72.48	79.55%	72.66%	86.43%

Figures7-8 and Table14-15 showed FROC curve and data source with detection persistence in time(the duration of a time a mark persists on the same target) as threshold for the dynamic video dataset and the third-party data.

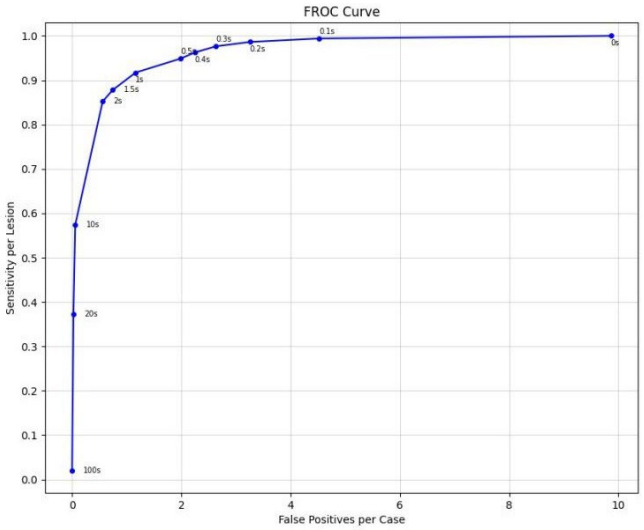

Figure 7: FROC Curve with Detection Persistence in Time as Threshold (dynamic video dataset)

Table 14: FROC Data source table with Detection Persistence in Time as Threshold (dynamic video dataset)

Detection persistence in time(ms)	FPC	95% CI-L	95% CI-U	Sensitivity per Lesion	95% CI-L	95% CI-U
>0	9.87	8.97	10.76	100.00%	100.00%	100.00%
>100	4.53	4.01	5.04	99.41%	98.74%	100.00%
>200	3.25	2.87	3.63	98.62%	97.60%	99.64%
>300	2.63	2.30	2.96	97.63%	96.31%	98.96%
>400	2.25	1.95	2.55	96.25%	94.60%	97.91%
>500	1.99	1.71	2.26	94.87%	92.95%	96.79%
>1000	1.16	0.98	1.35	91.72%	89.32%	94.12%
>1500	0.74	0.60	0.88	87.77%	84.92%	90.62%
>2000	0.56	0.45	0.67	85.21%	82.12%	88.30%
>10000	0.06	0.03	0.09	57.40%	53.09%	61.70%
>20000	0.02	0.00	0.04	37.28%	33.07%	41.49%
>100000	0	0	0	1.97%	0.76%	3.18%

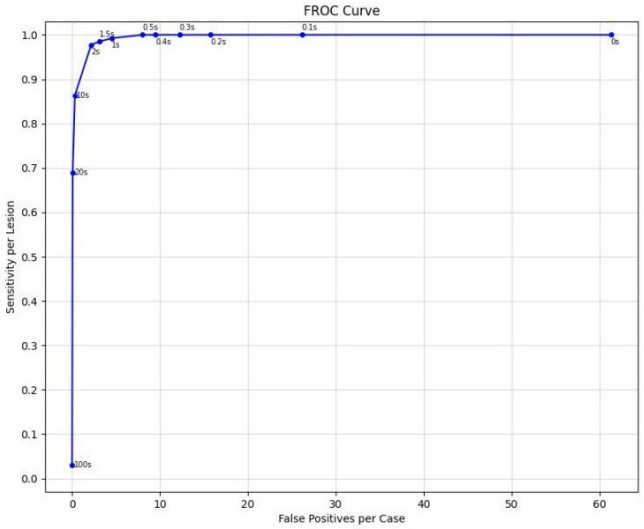

Figure 8: FROC Curve with Detection Persistence in Time as Threshold(third-party data)

Table 15: FROC Data source table with Detection Persistence in Time as Threshold(third-party data)

Detection persistence in time(ms)	FPC	95% CI-L	95% CI-U	Sensitivity per Lesion	95% CI-L	95% CI-U
>0	61.30	50.12	72.48	100.00%	100.00%	100.00%
>100	26.15	20.97	31.33	100.00%	100.00%	100.00%
>200	15.77	12.52	19.01	100.00%	100.00%	100.00%
>300	12.22	9.47	14.97	100.00%	100.00%	100.00%
>400	9.48	7.38	11.58	100.00%	100.00%	100.00%
>500	8.02	6.20	9.83	100.00%	100.00%	100.00%
>1000	4.50	3.43	5.57	99.24%	97.76%	100.00%
>1500	3.12	2.30	3.93	98.48%	96.40%	100.00%
>2000	2.17	1.56	2.77	97.73%	95.18%	100.00%
>10000	0.32	0.15	0.49	86.36%	80.51%	92.22%
>20000	0.07	0.00	0.13	68.94%	61.05%	76.83%
>100000	0	0	0	3.03%	0.11%	5.95%

An activation-time criterion consistent with the predicate device was incorporated into the TP definition: only lesions detected within less than 300 ms were classified as TP. Lesions with an activation time of 300 ms or longer were classified as FN for this analysis

Table 16: Detection Performance for Dynamic Video Dataset and Third-Party Data

Dataset	Mean Activation Time [95% CI]	FPC(False Positives per Case) [95% CI]	Sensitivity [95% CI]
Dynamic Video Dataset	**109ms [101ms, 118ms]**	**9.87 [8.97, 10.76]**	**89.94% [87.32%, 92.56%]**
Third-Party Data	**117ms [98ms, 134ms]**	**61.30 [50.12, 72.48]**	**87.88% [82.31T, 93.45%]**

- **Standalone Performance Conclusions**

Based on the above results, CAD - Lower GI met the pre-defined performance criteria in both modes and demonstrated high values across all subgroups. The test results were observed to be as expected and support that the device has similar performance to the predicate device.

- **Special Control Testing**
  - Pixel-level comparison of degradation of image quality due to the device: The maximum color error of image quality degradation caused by device is 0.78, which is only slightly recognizable to human eyes.
  - Assessment of video delay due to marker annotation: The maximum annotation delay is 38ms.
  - Assessment of real-time endoscopic video delay due to the device: The maximum real-time video delay is 30ms. The video delay was determined to be acceptable based on the results of the clinical study.
- **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 CAD - Lower GI system is safe for its intended use.

IX Clinical Tests

- **Study Design and Population**

A prospective, multicenter, randomized, parallel two-arm controlled trial was conducted at four academic medical centers in China (Peking Union Medical College Hospital, Nanfang Hospital, Huadong Hospital, and the First Affiliated Hospital of Bengbu Medical College) to evaluate the clinical performance of the CAD - Lower GI system. A total of 840 subjects were randomized in a 1:1 ratio via center-stratified block randomization (block size = 4) to either the Experimental arm (colonoscopy with real-time CAD - Lower GI assistance) or the Control arm (standard colonoscopy without CAD assistance). To eliminate learning bias, all participating endoscopists were pre-assigned to a fixed single arm for the entire study duration. The study enrolled adult patients (≥18 years) undergoing screening or surveillance colonoscopy. Key exclusion criteria included prior colorectal cancer, known polyposis syndromes, active inflammatory bowel disease, inadequate bowel preparation (Boston Bowel Preparation Scale <6), and withdrawal time <8 minutes.

- **Reference Standard (Sole Gold Standard)**

Histopathology, independently read by site panels of three blinded expert gastrointestinal pathologists with central adjudication of discordant cases by a senior gastrointestinal pathologist, served as the reference standard for efficacy evaluations. Diagnostic histopathology was evaluable for 916 of 923 resected or biopsied lesions: 568 of 571 Experimental lesions and 348 of 352 Control lesions. The seven missing histopathology results were handled using the prespecified multiple-imputation and sensitivity analyses. Evaluable lesions were classified according to the Revised Vienna Classification, and the reference-standard procedures were applied uniformly across study arms.

- **Analysis Populations**

The following analysis populations were defined per ICH E9:

- **Full Analysis Set (FAS)** : 824 subjects (412 Experimental, 412 Control) — all randomized subjects who underwent the allocated colonoscopy procedure.
- **Per-Protocol Set (PPS)** : 798 subjects (399 per arm) — FAS subjects without major protocol deviations.
- **Safety Set (SS)** : 840 subjects (420 per arm) — all randomized subjects who underwent the procedure.
- **NBI Sub-population** : 477 subjects (245 Experimental, 232 Control) — subjects in whom Narrow Band Imaging (NBI) mode was utilized during the procedure.

- **Demographic and Baseline Characteristics (FAS, n=824)**

The randomization achieved successful balance across arms, with all standardized differences <0.10. The mean age was 55.5 years (SD 11.9); 52.4% were male; 100% were Asian (Han Chinese); mean BMI was 25.7 kg/m^2.

Indication distribution was 64.4% screening and 35.6% surveillance. Image processor distribution was 58.5% Olympus CV-190 and 41.5% Olympus CV-1500, balanced across arms. Other baseline characteristics (ASA class, smoking status, family history of colorectal cancer, medication use, and sedation type) were also well balanced.

- **Procedure Quality Metrics**

Procedure quality met or exceeded ASGE/ACG 2024 benchmarks in both arms and was balanced, supporting the internal validity of the comparison:

- Cecal intubation rate: 99.3% (Experimental) vs. 99.0% (Control).
- Mean withdrawal time: 11.2 min (SD 2.1) vs. 10.8 min (SD 2.0); 98.8% vs. 99.0% of procedures met the ⩾8 min standard.
- Mean BBPS score: 7.7 (SD 1.1) vs. 7.6 (SD 1.0); adequate preparation (BBPS ⩾6) rate: 99.3% in both arms.
- Rectal retroflexion performed: 96.1% vs. 95.4%.

- **Efficacy Endpoints and Definitions**

The study employed an Intersection-Union Test (IUT) framework with two co-primary endpoints, both of which were required to independently succeed for trial success (familywise error rate controlled at alpha = 0.05; no multiplicity adjustment per FDA Multiple Endpoints Guidance, 2022).

- **Co-Primary Endpoint 1 — Adenoma Detection Rate (ADR, Case-Level)**

Defined as the proportion of patients with at least one histopathologically confirmed adenoma (Vienna classification categories 3 or 4.1). Superiority design with a prespecified margin of +5 percentage points (i.e., lower bound of the 95% confidence interval for the difference must exceed +5 pp). Statistical analysis used the Cochran-Mantel-Haenszel (CMH) method stratified by study site.

- **Co-Primary Endpoint 2 — Positive Predictive Agreement (PPA, Lesion-Level)**

Defined as the proportion of clinically significant lesions, including adenomas, adenocarcinomas, sessile serrated lesions (SSLs), and proximal hyperplastic polyps >=5 mm, among all biopsied or resected lesions. Non-inferiority was assessed against a -10 percentage-point margin using patient-cluster bootstrap confidence intervals (B=2,000). Missing lesion histopathology was addressed by multiple imputation (M=5), with complete-case and actual-arm worst-case analyses used to assess robustness.

- **Secondary Endpoint — Adenomas Per Colonoscopy (APC)**

Defined as the total number of histopathologically confirmed adenomas divided by the total number of procedures. Superiority design with a margin of 0 (i.e., lower bound of the 95% confidence interval for the difference must exceed 0). Statistical analysis used a mixed-effects Poisson regression model with study site as a random effect; negative binomial was prespecified as a sensitivity analysis if overdispersion was observed (Pearson chi^2 /df >1.5).

- **Exploratory Endpoints (not formally hypothesis-tested)**

Additional exploratory endpoints included Polyp Detection Rate (PDR), Neoplastic Lesion Detection Rate, Serrated Lesion Detection Rate, and false positive rates, all based on histopathological confirmation.

- **Co-Primary Endpoint Results (FAS, n = 824)**

ADR (Superiority) :

- Experimental: 51.2% (211/412 patients with ⩾1 adenoma).
- Control: 36.4% (150/412 patients with ⩾1 adenoma).
- CMH-adjusted difference: +14.8 percentage points (95% CI: 8.1, 21.5).
- The lower bound of the 95% CI (8.1 pp) exceeded the prespecified superiority margin of +5.0 pp →

SUPERIORITY ACHIEVED.

PPA (Non-inferiority) :

- Experimental: 81.2% (461 clinically significant lesions out of 568 total biopsied/resected lesions).
- Control: 82.5% (287 out of 348).
- Experimental-minus-Control difference: -1.3 percentage points.
- Cluster-bootstrap 95% CI (percentile): -5.8 to 3.2.
- The lower confidence limit (-5.8 pp) exceeded the prespecified non-inferiority margin of -10.0 pp -> NON-INFERIORITY ACHIEVED.
- Sensitivity (missing data) analyses were consistent: the multiple imputation (M=5) result was difference -1.4 pp (95% CI -6.0, 3.3) ; the actual-arm worst-case difference was -1.9 pp (95% CI -7.1, 3.1).

- **Secondary Endpoint Results (FAS, n = 824)**

APC (Superiority) :

- Experimental: 1.027 adenomas per procedure (423 total adenomas / 412 procedures).
- Control: 0.609 (251 total adenomas / 412 procedures).
- Mixed-Poisson difference: +0.418 (95% CI: 0.26, 0.57).
- The lower bound of the 95% CI (0.26) exceeded the superiority margin of 0 → SUPERIORITY ACHIEVED.
- Overdispersion parameter (chi ² /df) was 1.21 (Experimental) and 1.14 (Control), both below the prespecified threshold of 1.5, confirming Poisson model appropriateness.

- **Lesion Histopathology Composition**

The histopathological breakdown of the 916 histopathology-evaluable biopsied/resected lesions (568 Experimental and 348 Control) was as follows. Seven additional lesions had missing histopathology results (3 Experimental and 4 Control).

Table 16: PPA: Histopathology-Evaluable Lesion Composition by Arm (FAS)

Lesion Category	Exp (n=568)	Ctrl (n=348)
Adenoma (Vienna 3, 4.1)	423 (74.5%)	251 (72.1%)
Adenocarcinoma (Vienna 4.2-5)	4 (0.7%)	3 (0.9%)
Sessile serrated lesion (SSL)	21 (3.7%)	17 (4.9%)
Proximal HP >=5 mm	13 (2.3%)	16 (4.6%)
Clinically significant subtotal	461 (81.2%)	287 (82.5%)
Hyperplastic (distal/<5 mm proximal)	79 (13.9%)	44 (12.6%)
Normal / inflammatory	21 (3.7%)	14 (4.0%)
Other benign	7 (1.2%)	3 (0.9%)

- **Characteristics of Detected Adenomas**

The incremental adenomas detected with CAD assistance were predominantly small, flat, and proximal — the categories most prone to being missed during standard white-light colonoscopy:

- Size <5 mm: Experimental 65.5% vs. Control 59.4% (+128 additional adenomas).
- Size 5-10 mm: 26.5% vs. 29.1% (+39).
- Size >10 mm: 8.0% vs. 11.6% (+5).
- Paris IIa (flat-elevated): 171 vs. 95 (+76).
- Proximal location: 54.6% vs. 51.0% (+103).
- Paris IIb/Ic (flat/depressed): 41 vs. 17 (+24).

- **CAD Detection Attribution (Experimental Arm Only)**

Within the Experimental arm, detection attribution was prospectively recorded per lesion:

- Identified by both endoscopist and CAD: 295 adenomas (69.7%).
- CAD-first (endoscopist had not yet flagged the lesion): 89 adenomas (21.0%) — representing the incremental detection mechanism.
- Endoscopist-only (CAD did not flag): 39 adenomas (9.2%).

The arm-level incremental effect was +172 additional adenomas detected in the Experimental arm versus Control (+68% relative increase).

- **Performance by Compatible Image Processor (CV-190 vs. CV-1500)**

Per the Indications for Use claim for compatibility with both Olympus processors, a prespecified subgroup analysis was performed:

Table 17: Co-Primary and Secondary Endpoints by Image Processor (FAS)

Processor / Endpoint	Exp	Ctrl	Difference	95% CI / note
CV-190 (n=482: 239/243)				
ADR	51.0%	36.2%	+14.8 pp	(7.2, 22.4) superior
PPA (lesion-level)	81.2%	82.8%	-1.6 pp	(-7.3, 4.1) non-inferior
APC	1.02	0.61	+0.41	(0.22, 0.60) superior
CV-1500 (n=342: 173/169)				
ADR	51.4%	36.7%	+14.7 pp	(5.6, 23.8) superior
PPA (lesion-level)	81.1%	82.1%	-1.0 pp	(-7.9, 5.9) non-inferior
APC	1.03	0.61	+0.42	(0.19, 0.65) superior
Processor-by-treatment interaction (ADR)				p = 0.99 (no difference)

Processor-by-treatment interaction for ADR: p = 0.99, confirming consistent device performance across both compatible processors.

- **NBI Sub-study Results**

Narrow Band Imaging (NBI) was used in a prespecified NBI-exposed subpopulation of 477 subjects in the Full Analysis Set, including 245 subjects in the Experimental arm and 232 subjects in the Control arm. NBI was activated when a suspected lesion was identified during withdrawal. The results in the NBI-exposed subpopulation were directionally consistent with the overall FAS results, as summarized below:

Table 18: NBI Sub-Study Results

Endpoint (NBI sub-pop.)	Exp (n=245)	Ctrl (n=232)	Diff (95% CI)
ADR	54.3%	38.4%	+15.9 (7.9, 23.9)
PPA (lesion-level)	80.7%	82.1%	-1.4 (-6.9, 4.1)
APC	1.09	0.66	+0.43 (0.21, 0.65)

These results provide supportive clinical evidence for the use of CAD - Lower GI during colonoscopy procedures in which NBI is used. Because NBI use was clinically triggered rather than randomized by imaging modality, the NBI results are interpreted as supportive subgroup evidence.

- **Pre-specified Subgroup Analyses (ADR)**

Treatment effects were directionally consistent across the evaluable prespecified subgroups. No significant

treatment-by-subgroup interaction was observed for the evaluable factors (all interaction p > 0.10), and no individual clinical site was identified as an outlier (Breslow-Day p = 0.78).

- **Sensitivity Analyses**

All primary and secondary endpoint conclusions were robust across multiple sensitivity analyses:

- Per-Protocol Set (PPS, n = 798) : ADR difference +14.3(95% CI: 7.4, 21.2); PPA difference -1.3(95% CI: -5.9, 3.3); APC difference +0.41 (95% CI: 0.25, 0.57).
- PPA missing-histopathology analyses (7 lesions: 3 Experimental and 4 Control): the prespecified M=5 result was -1.4 pp (95% CI -6.0, 3.3), and the completed actual-arm worst-case result was -1.9 pp (95% CI -7.1, 3.1); both confirmed non-inferiority.
- ADR missing-case assessment: all 412 FAS patients in each arm had a determinable ADR outcome; no ADR outcomes were imputed. CTR Table 5 is the observed FAS analysis, not an all-randomized worst-case analysis. An extreme all-randomized sensitivity analysis gave a site-stratified CMH difference of 12.6 pp (95% CI 6.0, 19.3), maintaining superiority.
- Additional supportive results were consistent: APC complete-case difference +0.42 (95% CI 0.26, 0.58), and complete-case PPA BCa bootstrap difference -1.3 pp (95% CI -5.7, 3.1).

- **Safety Evaluation**

All 840 randomized subjects were included in the Safety Set. Day-30 follow-up was completed for 836/840 subjects (99.5%).

- **Adverse Events (AEs)**

- Any AE: Experimental 5.7% (24/420) vs. Control 5.2% (22/420) — low and balanced.
- Most common AEs: abdominal discomfort/cramping, post-polypectomy bleeding (minor, all managed conservatively or with clipping), nausea/vomiting, and vasovagal reactions. All AEs were consistent with routine colonoscopy-related events.

- **Serious Adverse Events (SAEs)**

- No deaths occurred during the study.
- Five SAEs were reported (3 Experimental, 2 Control), all CTCAE Grade 3 and all resolved without sequelae. None were assessed as device-related; all were attributed to routine colonoscopy complications (post-polypectomy bleeding, sedation-related vasovagal syncope, or cardiac arrhythmia).

- **Device Deficiencies**

Five minor, transient device deficiencies were recorded in the Experimental arm (e.g., transient false-positive bursts lasting ~1.5 seconds, momentary frame freezes lasting ~2 seconds, bounding-box drift on repositioning). All events self-resolved within 3 seconds without any harm to subjects. No algorithm modifications were made during the trial.

Safety Conclusion: CAD - Lower GI demonstrated a favorable safety profile with no device-related AEs or SAEs and no evidence of increased procedural risk.

- **Clinical Conclusions**

In this histopathology-referenced randomized controlled trial, CAD - Lower GI met all pre-specified co-primary and secondary efficacy endpoints:

- ADR superiority was demonstrated with a +14.8 pp absolute improvement (95% CI 8.1, 21.5), exceeding the +5 pp margin. No FAS ADR outcomes were missing or imputed; the all-randomized extreme sensitivity analysis was also superior at +12.6 pp (95% CI 6.0, 19.3).
- PPA non-inferiority was demonstrated in the prespecified M=5 analysis with a difference of -1.4 pp (95% CI -6.0, 3.3). The complete-case result [-1.3 pp (95% CI -5.8, 3.2)] and actual-arm worst-case result [-1.9 pp (95% CI -7.1, 3.1)] were consistent with this conclusion.
- APC superiority was demonstrated with a difference of +0.418 (95% CI: 0.26, 0.57), exceeding the 0 margin.

The primary and secondary efficacy conclusions were consistent across both compatible Olympus image processors, CV-190 and CV-1500. Results in the NBI-exposed subpopulation were directionally consistent with the overall FAS results and provide supportive evidence for use of the device during procedures in which NBI is used.
The safety profile was favorable, with no device-related adverse events or serious adverse events and only minor transient device deficiencies without subject harm.

Collectively, these clinical data support the conclusion that CAD - Lower GI is clinically effective and safe for its intended use as a real-time computer-assisted detection tool to aid qualified endoscopists in detecting suspected colonic mucosal lesions during colorectal endoscopy under both white-light and NBI imaging modalities, with histopathology as the definitive reference standard.

X Conclusion

Based on the intended use, technological characteristics, performance results, and comparison to the predicate, the subject CAD - Lower GI has been shown to be substantially equivalent to the predicate device identified in this submission and does not present any new issues of safety or effectiveness.