



September 25, 2026

CapsoVision, Inc.
Zane Liu
Director, Regulatory Affairs
18805 Cox Avenue, Suite 250
Saratoga, California 95070

Re: K254230

Trade/Device Name: CapsoView (CVV); CapsoCloud (CLD)
Regulation Number: 21 CFR 876.1540
Regulation Name: Gastrointestinal Capsule Endoscopy Analysis Software Device
Regulatory Class: Class II
Product Code: QZF
Dated: August 26, 2026
Received: August 26, 2026

Dear Zane Liu:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding

When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SIVAKAMI VENKATACHALAM -S

for

Shanil P. Haugen, Ph.D.

Assistant Director

DHT3A: Division of Renal, Gastrointestinal,
Obesity, and Transplant Devices

OHT3: Office of Gastrorenal, ObGyn,

General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K254230

Device Name

CapsoView (CVV)

CapsoCloud (CLD)

Indications for Use (Describe)

CapsoView is a software application for the download, transcode, and review of videos from CapsoCam Plus Capsule Endoscopes, and the generation of capsule endoscopy reports.

CapsoCloud is a cloud-based software application for the review of videos from CapsoCam Plus Capsule Endoscopes, and the generation of capsule endoscopy reports.

The software includes artificial intelligence (AI) tools for video analysis designed to aid clinicians in the review of small bowel capsule endoscopy images collected from adult and pediatric patients over two years of age, in whom the capsule endoscopy images were obtained for suspected small bowel bleeding. The "AI Highlights" tool aids small bowel capsule endoscopy reviewers by decreasing the time to review capsule endoscopy images. The "Suggested Landmarks" tool assists reviewers in the identification of the digestive tract location (esophagus, stomach, small bowel, and colon). The "Green Detection" tool identifies and sequesters obscured, uninterpretable frames (e.g., obscured by debris, bile, or bubbles) to streamline the review process.

The AI tools are not intended to replace the clinician's diagnostic interpretation. Clinicians are responsible for conducting their own assessment of the AI-assisted findings by reviewing the entire video as clinically appropriate.

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

510(k) #: K254230

Prepared on: September 24, 2026

Contact Details:

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name: CapsoView (CVV)
CapsoCloud (CLD)

Common Name: Gastrointestinal capsule endoscopy analysis software device

Classification Name: Gastrointestinal Capsule Endoscopy Analysis Software Device

Regulation Number: 876.1540

Product Code(s): QZF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Primary Predicate Device: Ankon Technologies Co., Ltd. NaviCam ProScan (DEN230027, Product Code: QZF)

Reference Device: DigestAID - Artificial Intelligence Development, S.A., Deep Capsule (K250655, Product Code: QZF)

Device Description Summary

21 CFR 807.92(a)(4)

This submission focuses on the introduction of an artificial intelligence (AI)-assisted reading tool to the CapsoView and CapsoCloud reading software for the CapsoCam Plus (SV-3) Capsule Endoscopy System (K242643, "CapsoCam Plus"). CapsoView is proprietary workstation software used with CapsoCam Plus to download, view, and generate reports from capsule endoscopy images. CapsoCloud is a cloud-based (Web or mobile App) software application used to manage procedures and, if videos are uploaded onto the platform, review images from CapsoCam Plus and generate capsule endoscopy reports. This submission does not involve any changes to the hardware components cleared under K242643.



The proposed artificial intelligence tools analyze capsule endoscopy images acquired by CapsoCam Plus to recognize and mark potential regions of interest, with the goal of reducing the time it takes small bowel capsule endoscopy reviewers to review capsule endoscopy images and to assist these reviewers in identifying the digestive tract location (oral cavity, esophagus, stomach, small bowel, cecum). These tools are:

- The AI Highlights feature recognizes and marks images containing suspected abnormal lesions. During analysis, images are classified in a binary matter as "abnormal" or "normal," and for suspected "abnormal" frames, bounding boxes are additionally overlaid to identify the suspected lesion region.
- The Suggested Landmarks feature identifies the specific segment of the gastrointestinal (GI) tract where an image was captured. By analyzing the capsule endoscopy video, this process can segment the video into distinct regions: esophagus, stomach, small bowel, and the regions before (ingestion and oral cavity) and after (cecum to excretion) the primary GI tract.
- The Green Detection feature identifies images obscured by debris with no visible mucosa for diagnostic interpretation (i.e., often green in color). Frames detected to be likely uninterpretable are hidden, but not deleted, from the capsule endoscopy video with the goal of improving efficiency of review.

Each classification task is performed through a separate machine learning algorithm trained on images captured by the CapsoCam Plus, including capsule endoscopy videos from real-world clinical use in the United States and those collected as a part of prior clinical studies involving the SV-3 capsule endoscope. These algorithms are run during the transcoding process for SV-3 videos on CapsoView. The outcomes of the AI analyses (e.g., predicted location, abnormality status, location of any bounding box overlays) are stored as metadata alongside the video file, which does not require the altering of any frame of the original video, and may be viewed with either CapsoView or CapsoCloud.

The AI analysis tools are not intended to replace gastroenterologist assessment or, where applicable, histopathological sampling.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

CapsoView is a software application for the download, transcode, and review of videos from CapsoCam Plus Capsule Endoscopes, and the generation of capsule endoscopy reports.

CapsoCloud is a cloud-based software application for the review of videos from CapsoCam Plus Capsule Endoscopes, and the generation of capsule endoscopy reports.

The software includes artificial intelligence (AI) tools for video analysis designed to aid clinicians in the review of small bowel capsule endoscopy images collected from adult and pediatric patients over two years of age, in whom the capsule endoscopy images were obtained for suspected small bowel bleeding. The "AI Highlights" tool aids small bowel capsule endoscopy reviewers by decreasing the time to review capsule endoscopy images. The "Suggested Landmarks" tool assists reviewers in the identification of the digestive tract location (esophagus, stomach, small bowel, and colon). The "Green Detection" tool identifies and



sequesters obscured, uninterpretable frames (e.g., obscured by debris, bile, or bubbles) to streamline the review process.

The AI tools are not intended to replace the clinician's diagnostic interpretation. Clinicians are responsible for conducting their own assessment of the AI-assisted findings by reviewing the entire video as clinically appropriate.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed device and predicate device have the same intended use, as both devices are intended to aid reviewers of capsule endoscopy videos to decrease the reading time. The intended users of the two devices are the same. Neither device is intended to replace decision making. Rather, in both devices, the analysis findings of the software are presented as potential areas of interest, and the clinician is responsible for conducting their own assessment of the findings of the AI-assisted reading through review of the entire video when deemed clinically appropriate.

The proposed device and predicate device have similar Indications for Use, each focused on the same claim of “reduction in reading time” and with the patient populations consisting of patients for whom capsule endoscopy was performed due to suspected bleeding. The primary difference in Indications for Use between the proposed device and the predicate device is with respect to intended patient population, which does not constitute a difference in intended use, but rather reflects the study population of each device.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device is similar to the predicate device with respect to technological characteristics. Both devices are AI-assisted reading tools for capsule endoscopy of the small bowel, built into the reading software of their respective capsule endoscopy systems, designed to analyze recorded videos and provide outputs which recognize and mark potential pathologies. For both devices, reading assistance is provided both directly, through the detection of suspected pathologies in the video, and indirectly, through the identification of frames of lower review priority (e.g., presumed “normal” frames and videos taken outside the small bowel). In both devices, potential pathologies are marked through a rectangular “bounding box” and regions without such detections remain unchanged. Both devices provide several “reading modes,” such that the user can filter through the video based on the detection outcome (e.g., frames with suspected pathology only) or to review the original video.

There are technological differences between the two devices, including within their respective neural network-based detection algorithms (e.g., the proposed device utilizes U.S. training data whereas the predicate device utilizes OUS [Chinese] data) and in the discrete classifications output by each device, but they do not raise different questions of safety or effectiveness. In both devices, the indicated patient population is consistent with that for which the underlying artificial intelligence algorithm has been developed and tested. Furthermore, as both devices provide the same form of reading assistance, their labeling each discloses the potential pathologies detectable by each device, neither device replaces clinical decision making, and the clinician retains the responsibility to exercise clinical judgment on the device findings through review of the full video, this technological difference in detectable pathology types thus does not raise different



questions of safety or effectiveness. As such, CapsoVision is of the opinion that the proposed device is substantially equivalent to the predicate device with respect to technological characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Software/Cybersecurity

CapsoVision has conducted comprehensive software verification and validation testing on both CapsoView and CapsoCloud. The results of these tests demonstrate that both software perform as intended, in accordance with their respective Software Requirements Specifications.

CapsoView/CapsoCloud was identified as having a basic level of concern as defined in the FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software documentation included:

1. Software Description
2. Risk Management File
3. Software Requirement Specification
4. System and Software Architecture Design
5. Software Design Specification
6. Software Development, Configuration Management, and Maintenance Practices
7. Software Testing as Part of Verification and Validation
8. Software Version History
9. Unresolved Software Anomalies

Risk analysis was provided for the software with a description of the hazards, their causes and severity as well as acceptable methods for control of the identified risks.

CapsoView/CapsoCloud provided a description, with test protocols including pass/fail criteria and report of results, of acceptable verification and validation activities at the unit, integration and system level. All testing met design specifications and passed successfully.

Cybersecurity documentation included recommended information from the FDA guidance document “FDA Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.” This includes threat identification, vulnerability assessment, likelihood and impact assessment, cybersecurity mitigation information, security policies and controls, continuous monitoring and review activities, regular auditing and cybersecurity testing.

Development Dataset and Ground Truth Establishment

All training and testing data used during the development phase are sourced from CapsoCloud, which consists of patient capsule endoscopy videos and reports acquired from real-world clinical use of the CapsoCam Plus, with a maximum of one capsule recording per patient. A total of



1,432 patients contributed to the developmental datasets, with a 2:1 partition by patient across the training and internal testing sets.

Following anonymization, initial screening is performed by CapsoVision staff to identify videos where the accompanying reports indicated the presence of pathology. Video clips of 7~11 consecutive frames are extracted based on this initial screen, and these clips are then provided to at least two experienced, independent capsule endoscopists for labeling. Only raw images, blinded from the keywords used for parsing, to the readers, with no text or any other information. The capsule endoscopists are asked to 1) draw contours of the pathologies and 2) select one of the 14 classes for each contour. Agreement between two independent labelers is required to confirm the label of the training data. A total of 8,176 confirmed positive images and 27,296 confirmed negative images were ultimately collected and labeled. **Table 1** below summarizes the demographic characteristics of the training and internal testing datasets.

Table 1. Comparison of Demographic Characteristics in Training and Internal Testing Datasets

	Training (n = 886 patients)	Internal Testing (n = 546 patients)
Number of Images		
Ground Truth Positive	5365	2811
Ground Truth Negative	17342	9954
Patients by Age		
0–5	1	0
6–12	6	8
13–21	42	16
22–39	64	51
40–59	180	127
60+	593	344
Patients by U.S. Census Region of Hospital/Clinic		
West	221	178
Midwest	99	60
South	471	257
Northeast	95	51
Patients by Finding^[1]		
<i>Classified “Abnormal”</i>	<i>464</i>	<i>260</i>
Angiodysplasia/angiectasia (AVM, ectasia)	206	97
Bleeding/blood	99	54
Ulcers or aphthoid erosion	151	93
Protruding Lesions (Polyps, Lipomas, Nodules, Masses)	79	42
Scalloped mucosa	9	5
Diverticulum	17	16
Edematous villi	13	11
<i>Classified “Normal”</i>	<i>675</i>	<i>420</i>
Normal Mucosa	365	195
Lymphangiectasia	163	104
Xanthoma	16	11
Phlebectasia	44	30
Duodenal Papilla	33	22



Erythema	195	131
Petechiae	139	66

^[1] The count represents the number of unique patients who contributed frames depicting a finding.

The AI Highlights feature recognizes and marks images containing suspected abnormal lesions. The software is specifically trained to recognize seven pathology types:

Angiodysplasia/angiectasia (AVM, ectasia), Bleeding/Blood, Ulcers or aphthoid erosion, Protruding Lesions (Polyps, Lipomas, Nodules, Masses), Scalloped mucosa, Diverticulum, and Edematous villi. During analysis, images are classified in a binary matter as "abnormal" or "normal," and for suspected "abnormal" frames, bounding boxes are additionally overlaid to identify the suspected lesion region. Although the device was trained on these specific pathology types, and is capable of recognizing potential small bowel pathologies, it was not validated to differentiate these pathologies.

Standalone/Clinical Performance Testing

Following completion of training and internal testing and locking of the device artificial intelligence algorithms which are the subject of the proposed device, CapsoVision has conducted comprehensive standalone and clinical performance testing on the artificial intelligence algorithms to evaluate both the detection performance of each algorithm, for their respective regions of interest, and the collective performance of these algorithms in assisting capsule endoscopists in the detection of clinically-relevant small bowel pathologies during capsule endoscopy to reduce the reading time of capsule endoscopy videos.

Study Population and Reference Standard:

The evaluation dataset consisted of 111 deidentified capsule endoscopy videos collected retrospectively from the commercial use of the CapsoCam Plus (SV-3) system in the United States via the CapsoCloud® platform. To ensure independence, the dataset had no patient-level overlap with the data used for algorithm training.

The population included both adult and pediatric patients from a diverse range of 70 U.S. hospitals and medical centers to ensure representation of real-world clinical practice. The patients ranged between 4 and 89 years of age at the time of procedure (Median: 49.5, SD: 28.1) with 33 patients in the pediatric subgroup and 78 in the adult subgroup. Table 2 presents the patient demographics and clinical characteristics.

Table 2. Summary of Study Population

Age, years	n	111
	Mean (SD)	49.5 (28.1)
	Median	61.0
	Min, Max	4.0, 89.0
Indication for Capsule Endoscopy	Bleeding	63 (57%)
	Non-Bleeding	45 (41%)
	Not Reported	3 (2%)
Finding of Blood, n (%)	Bleeding	72 (65%)
	No Bleeding	39 (35%)

Age group, n (%)	4 – 5	5 (5%)
	6 – 12	12 (11%)
	13 – 21	16 (14%)
	22 – 39	8 (7%)
	40 - 59	13 (12%)
	60+	57 (51%)
Gender	Male	13 (12%)
	Female	18 (16%)
	Unknown	80 (72%)
U.S. Census Region of Original Site	West	43 (38.7%)
	Midwest	21 (18.9%)
	South	34 (30.6%)
	Northeast	13 (11.7%)

A "ground truth" reference standard for 1) the presence of pathology (AI Highlights), 2) the presence of obstructing debris (green detection), and 3) GI landmark locations (Suggested Landmarks), was established by a panel of independent, expert gastroenterologists utilizing a consensus methodology. Following this process, 82 videos were found with at least one clinically-relevant pathology and 29 videos included no such pathology. A total of 6,073 green frames were identified across the videos. Duodenal and cecal landmarks were established for all 111 videos. The esophageal landmark was established for 98 videos. The gastric landmark was established for 100 videos.

Standalone Performance Assessment

A standalone performance assessment was conducted to characterize the accuracy of the software's algorithms (Pathology Detection, Green Detection, and Landmark Segmentation) independent of clinician interaction.

The algorithms were tested against a statistically powered dataset of videos independent of the training data. Performance was evaluated against the expert consensus reference standard. The results of the study were as follows:

- Pathology Detection (AI Highlights):** The algorithm achieved a per-patient sensitivity of 100% (95% CI: 95.60%, 100%) and a per-patient specificity of 0% (95% CI: 0.00%, 11.94%). As the algorithm is designed to recommend frames for every video for consideration by the physician, this specificity result was expected. The per-frame sensitivity was observed at 85.34% (95% CI: 71.98%, 90.89%) and per-frame specificity was observed at 87.29% (95% CI: 85.39%, 89.07%). Bounding box accuracy in a random sampling of 2,368 true positive frames was observed at 98.09% (95% CI: 96.93%, 98.92%).
- Green Detection:** The algorithm achieved a specificity of 98.88% (95% CI: 98.38%, 99.29%) and a sensitivity of 68.86% (95% CI: 61.59%, 76.13%) for identifying obscured frames.



- Landmark Segmentation (Suggested Landmarks):** Table 3 presents the sensitivity and specificity for detecting each GI segment (oral cavity, esophagus, stomach, small bowel, and colon). Please note that for patients for whom the capsule was delivered endoscopically, the upper GI (oral cavity, esophagus, and stomach) landmarks may not be visible, depending on the location of endoscopic delivery.

Table 3. Summary of Landmark Segmentation Algorithm Performance

GI Segment	Sample Size (n)	Sensitivity (95% CI)	Specificity (95% CI)
Oral Cavity	98	74.82% (61.41%, 85.91%)	99.51% (99.02%, 99.82%)
Esophagus	98	72.68% (47.53%, 85.89%)	99.41% (98.90%, 99.81%)
Stomach	100	59.83% (50.07%, 68.73%)	99.44% (98.87%, 99.87%)
Small Bowel	111	94.78% (91.96%, 97.20%)	90.97% (87.98%, 93.60%)
Colon	111	99.38% (98.88%, 99.76%)	96.77% (94.71%, 98.43%)

Considering that the user interface of CapsoView/CapsoCloud require the confirmation of each “landmark” at the beginning of video review, performance of the algorithm is acceptable for providing an initial recommendation to a trained capsule reader. Lower sensitivity in early GI segments (e.g., stomach) is expected in real-world capsule endoscopy due to rapid bolus transit, variable gastric distension, or un-prepped mucosal debris. In addition, the sensitivities and specificities for the comparable feature within the predicate device, NaviCam ProScan (DEN230027), represent the results from internal testing utilizing a “split” of patients from the same dataset used for algorithm training, which was enrolled solely from OUS [Chinese] sites. Furthermore, data suitable for training typically requires a high quality of bowel cleanliness, which does not reflect real-world capsule endoscopy conditions. As such, the reported sensitivity and specificity figures may overestimate the real-world performance of the feature, as would be reflected if such testing had been conducted on a fully independent, U.S. clinical cohort, as was executed for the proposed device.

In addition, subgroup analyses were performed for each endpoint by region (Midwest, West, Northeast, and South U.S., per U.S. Census Bureau regions), bowel preparation quality, patient age, patient gender, indications for imaging (bleeding related vs. not), and presence of blood in findings (found vs. not). The following presents the detailed subgroup analyses conducted as a part of the standalone performance tests for Pathology Detection (Table 4 [patient] and Table 5 [frame]), Green Detection (Table 6), and Landmark Segmentation for the Small Bowel (Table 7).

Table 4. Standalone Study Outcomes for the Pathology Detection Algorithm (Patient-Level)

	Total / Positive / Negative Patient Count			Sensitivity	Specificity ^[1]
Overall	Total: 111	Positive	Negative	100.00 [95.60, 100.00]	0.00 [0.00, 11.94]
	Ground Truth	82	29		
	AI	111	0		
Subgroup – U.S. Region					
Midwest	Total: 21	Positive	Negative	100.00 [79.41, 100.00]	0.00 [0.00, 52.18]
	Ground Truth	16	5		
	AI	21	0		



	Total / Positive / Negative Patient Count			Sensitivity	Specificity ^[1]
Northeast	Total: 13	Positive	Negative	100.00 [73.54, 100.00]	0.00 [0.00, 97.50]
	Ground Truth	12	1		
	AI	13	0		
South	Total: 34	Positive	Negative	100.00 [87.66, 100.00]	0.00 [0.00, 45.93]
	Ground Truth	28	6		
	AI	34	0		
West	Total: 43	Positive	Negative	100.00 [86.77, 100.00]	0.00 [0.00, 19.51]
	Ground Truth	26	17		
	AI	43	0		
Subgroup – Bowel Prep					
Fair	Total:36	Positive	Negative	100.00 [88.43, 100.00]	0.00 [0.00, 45.93]
	Ground Truth	30	6		
	AI	36	0		
Poor	Total: 1	Positive	Negative	N/A ^[2]	N/A ^[2]
	Ground Truth	1	0		
	AI	1	0		
Good	Total: 74	Positive	Negative	100.00 [93.02, 100.00]	0.00 [0.00, 14.82]
	Ground Truth	51	23		
	AI	74	0		
Subgroup – Age					
2-5	Total: 5	Positive	Negative	100.00 [47.82, 100.00]	N/A ^[2]
	Ground Truth	5	0		
	AI	5	0		
6-12	Total: 12	Positive	Negative	100.00 [63.06, 100.00]	0.00 [0.00, 60.24]
	Ground Truth	8	4		
	AI	12	0		
13-21	Total: 16	Positive	Negative	100.00 [66.37, 100.00]	0.00 [0.00, 40.96]
	Ground Truth	9	7		
	AI	16	0		
22-39	Total: 8	Positive	Negative	100.00 [29.24, 100.00]	0.00 [0.00, 52.18]
	Ground Truth	3	5		
	AI	8	0		
40-59	Total: 13	Positive	Negative	100.00 [71.51, 100.00]	0.00 [0.00, 84.19]
	Ground Truth	11	2		
	AI	13	0		
60+	Total: 57	Positive	Negative	100.00 [92.29, 100.00]	0.00 [0.00, 28.49]
	Ground Truth	46	11		
	AI	57	0		
Subgroup – Gender					
Male	Total: 13	Positive	Negative	100.00 [66.37, 100.00]	0.00 [0.00, 60.24]
	Ground Truth	9	4		
	AI	13	0		
Female	Total: 18	Positive	Negative	100.00 [71.51, 100.00]	0.00 [0.00, 40.96]
	Ground Truth	11	7		
	AI	18	0		
Unknown	Total:80	Positive	Negative	100.00 [94.22, 100.00]	0.00 [0.00, 18.53]
	Ground Truth	62	18		
	AI	80	0		
Subgroup – Indications for Imaging					



	Total / Positive / Negative Patient Count			Sensitivity	Specificity ^[1]
Bleeding	Total: 63	Positive	Negative	100.00 [92.89, 100.00]	0.00 [0.00, 24.71]
	Ground Truth	50	13		
	AI	63	0		
No Bleeding	Total: 45	Positive	Negative	100.00 [88.78, 100.00]	0.00 [0.00, 23.16]
	Ground Truth	31	14		
	AI	45	0		
Unknown	Total: 3	Positive	Negative	100.00 [2.50, 100.00]	0.00 [0.00, 84.19]
	Ground Truth	1	2		
	AI	3	0		
Subgroup – Finding of Bleeding					
Bleeding	Total: 72	Positive	Negative	100.00 [94.04, 100.00]	0.00 [0.00, 26.46]
	Ground Truth	60	12		
	AI	72	0		
No Bleeding	Total: 39	Positive	Negative	100.00 [84.56, 100.00]	0.00 [0.00, 19.51]
	Ground Truth	22	17		
	AI	39	0		

[1]: All patients were false positives; therefore, a bootstrap CI was not computed, and an exact Clopper-Pearson CI is reported.

[2]: Insufficient number for calculation.

Table 5. Standalone Study Outcomes for the Pathology Detection Algorithm (Frame-Level)

	Total / Positive / Negative Frame Count			Sensitivity	Bounding Box Accuracy	Specificit y
Overall	Total: 1,920,609	Positiv e	Negative	85.34 [71.98, 90.89]	98.09 [96.93, 98.92]	87.29 (85.38, 89.07)
	Ground Truth	26,930	1,893,679			
	AI	263,617	1,656,992			
	Bounding Box	2,368	N/A			
Subgroup – U.S. Region						
Midwest	Total: 398,846	Positiv e	Negative	89.81 [74.82, 95.65]	99.15 [98.37, 100.00]	85.81 [81.34, 90.38]
	Ground Truth	6,555	392,291			
	AI	61,526	337,320			
	Bounding Box	818	N/A			
Northeast	Total: 226,277	Positiv e	Negative	48.31 [17.02, 95.63]	98.28 [93.71, 100.00]	89.24 [86.17, 92.32]
	Ground Truth	1,629	224,648			
	AI	24,951	201,326			
	Bounding Box	174	N/A			
South	Total: 659,390	Positiv e	Negative	87.72 [71.05, 94.43]	98.81 [97.61, 99.66]	88.26 [84.6, 91.55]
	Ground Truth	5,790	653,600			
	AI	81,794	577,596			
	Bounding Box	852	N/A			



	Total / Positive / Negative Frame Count			Sensitivity	Bounding Box Accuracy	Specificity
West	Total: 636,096	Positive	Negative	86.67 [57.59, 91.75]	95.24 [91.81, 98.07]	86.50 [83.35, 89.13]
	Ground Truth	12,956	623,140			
	AI	95,346	540,750			
	Bounding Box	524	N/A			
Subgroup – Bowel Prep						
Poor	Total: 12,271	Positive	Negative	89.23 [89.23, 89.23]	100.00 [100.00, 100.00]	N/A [2]
	Ground Truth	65	12,206			
	AI	1,362	10,909			
	Bounding Box	22	N/A			
Fair	Total: 681,621	Positive	Negative	89.31 [76.36, 94.61]	98.04 [96.03, 99.14]	82.40 [79.26, 85.32]
	Ground Truth	12,524	669,097			
	AI	128,889	552,732			
	Bounding Box	1,375	N/A			
Good	Total: 1,226,717	Positive	Negative	81.86 [52.4, 90.14]	98.13 [96.61, 99.27]	89.97 [87.78, 91.89]
	Ground Truth	14,341	1,212,376			
	AI	133,366	1,093,351			
	Bounding Box	971	N/A			
Subgroup – Age						
2-5	Total: 115,863	Positive	Negative	85.84 [81.75, 98.80]	99.44 [98.98, 100.00]	77.71 [69.98, 86.13]
	Ground Truth	1,963	113,900			
	AI	27,058	88,805			
	Bounding Box	179	N/A			
6-12	Total: 154,651	Positive	Negative	80.09 [50.46, 93.79]	94.12 [89.54, 97.87]	79.28 [71.85, 84.31]
	Ground Truth	3,727	150,924			
	AI	34,253	120,398			
	Bounding Box	286	N/A			
13-21	Total: 265,422	Positive	Negative	40.52 [24.15, 72.03]	94.34 [78.26, 100.00]	90.64 [89.36, 91.92]
	Ground Truth	575	264,847			
	AI	25,022	240,400			
	Bounding Box	106	N/A			
22-39	Total: 105,570	Positive	Negative	92.42 [50.00, 92.49]	96.83 [96.36, 100.00]	92.94 [88.68, 94.7]
	Ground Truth	8,416	97,154			
	AI	14,628	90,942			
	Bounding Box	62	N/A			
40-59	Total: 209,518	Positive	Negative	95.41 [73.59, 96.66]	99.30 [96.83, 100.00]	82.17 [73.95, 90.56]
	Ground Truth	3,920	205,598			
	AI	40,390	169,128			
	Bounding Box	426	N/A			

	Total / Positive / Negative Frame Count			Sensitivity	Bounding Box Accuracy	Specificity
60+	Total: 1,069,585	Positive	Negative	78.77 [55.68, 91.72]	98.77 [97.92, 99.52]	89.1 [86.96, 91.08]
	Ground Truth	8,329	1,061,256			
	AI	122,266	947,319			
	Bounding Box	1,309	N/A			
Subgroup – Gender						
Male	Total: 202,807	Positive	Negative	75.74 [46.64, 92.58]	95.90 [92.47, 98.56]	82.60 [74.82, 88.55]
	Ground Truth	2,403	200,404			
	AI	36,692	166,115			
	Bounding Box	269	N/A			
Female	Total: 269,070	Positive	Negative	84.38 [38.62, 97.26]	95.21 [89.22, 100.00]	87.82 [83.96, 90.69]
	Ground Truth	1,799	267,271			
	AI	34,059	235,011			
	Bounding Box	165	N/A			
Unknown	Total: 1,448,732	Positive	Negative	86.43 [70.23, 92.07]	98.65 [97.65, 99.33]	87.85 [85.63, 89.96]
	Ground Truth	22,728	1,426,004			
	AI	192,866	1,255,866			
	Bounding Box	1,934	N/A			
Subgroup – Indications for Imaging						
Bleeding	Total: 1,090,684	Positive	Negative	86.25 [59.18, 92.55]	98.79 [97.85, 99.42]	89.14 [86.81, 91.25]
	Ground Truth	16,960	1,073,724			
	AI	131,212	959,472			
	Bounding Box	1,339	N/A			
No Bleeding	Total: 773,830	Positive	Negative	85.70 [72.33, 92.86]	97.66 [95.63, 99.06]	84.64 [81.39, 87.66]
	Ground Truth	9,693	764,137			
	AI	125,633	648,197			
	Bounding Box	1,023	N/A			
Unknown	Total: 56,095	Positive	Negative	16.97 [16.97, 16.97]	28.57 [28.57, 28.57]	87.95 [80.72, 93.83]
	Ground Truth	277	55,818			
	AI	6,772	49,323			
	Bounding Box	6	N/A			
Subgroup – Finding of Bleeding						
Bleeding	Total: 1,303,755	Positive	Negative	83.29 [68.58, 91.26]	98.29 [97.06, 99.12]	84.81 [82.32, 87.17]
	Ground Truth	17,226	1,286,529			



	Total / Positive / Negative Frame Count			Sensitivity	Bounding Box Accuracy	Specificity
No Bleeding	AI	209,725	1,094,030	88.98 [47.64, 92.58]	97.07 [92.93, 99.27]	92.54 [91.18, 93.82]
	Bounding Box	1,990	N/A			
	Total: 616,854	Positive	Negative			
	Ground Truth	9,704	607,150			
	AI	53,892	562,962			
	Bounding Box	378	N/A			

[1]: As all patients were false positives, a bootstrap confidence interval was not computed, and an exact confidence interval is reported.

[2]: Analysis not conducted for the bowel prep poor subgroup as it comprised of one patient.

Table 6. Standalone Study Outcomes for the Green Detection Algorithm (Frame-Level)

	Total / Green / Not Green Frame Count			Sensitivity	Specificity
Overall	Total: 1,920,609	Green	Not Green	68.86 [61.59, 76.13]	98.88 [98.38, 99.29]
	Ground Truth	6,073	1,914,536		
	AI	25,665	1,894,944		
Subgroup – U.S. Region					
Midwest	Total: 398,846	Green	Not Green	65.98 [51.30, 86.83]	99.10 [98.41, 99.63]
	Ground Truth	823	398,023		
	AI	4,133	394,713		
Northeast	Total: 226,277	Green	Not Green	90.82 [60.13, 97.22]	98.57 [97.20, 99.66]
	Ground Truth	523	225,754		
	AI	3,699	222,578		
South	Total: 659,390	Green	Not Green	72.10 [43.14, 88.65]	98.15 [96.88, 99.14]
	Ground Truth	3,308	656,082		
	AI	14,492	644,898		
West	Total: 636,096	Green	Not Green	54.90 [31.76, 79.41]	99.60 [99.32, 99.81]
	Ground Truth	1,419	634,677		
	AI	3,341	632,755		
Subgroup – Bowel Prep					
Poor	Total: 12,271	Green	Not Green	N/A ^[1]	N/A ^[1]
	Ground Truth	153	12,118		
	AI	3,106	9,165		
Fair	Total: 681,621	Green	Not Green	71.59 [54.99, 83.84]	98.52 [97.76, 99.14]
	Ground Truth	4,755	676,866		
	AI	13,421	668,200		
Good	Total: 1,226,717	Green	Not Green	53.91 [19.46, 87.58]	99.31 [98.91, 99.64]
	Ground Truth	1,165	1,225,552		
	AI	9,138	1,217,579		
Subgroup – Age					

	Total / Green / Not Green Frame Count			Sensitivity	Specificity
2-5	Total: 115,863	Green	Not Green	69.34 [63.21, 86.92]	99.00 [98.37, 99.65]
	Ground Truth	486	115,377		
	AI	1,492	114,371		
6-12	Total: 154,651	Green	Not Green	22.36 [14.96, 59.24]	99.85 [99.74, 99.94]
	Ground Truth	559	154,092		
	AI	357	154,294		
13-21	Total: 265,422	Green	Not Green	81.18 [31.71, 91.02]	99.88 [99.75, 99.97]
	Ground Truth	186	265,236		
	AI	481	264,941		
22-39	Total: 105,570	Green	Not Green	44.44 [30.0, 47.73]	99.47 [98.74, 99.86]
	Ground Truth	54	105,516		
	AI	586	104,984		
40-59	Total: 209,518	Green	Not Green	28.79 [8.07, 71.86]	99.39 [98.85, 99.75]
	Ground Truth	771	208,747		
	AI	1,488	208,030		
60+	Total: 1,069,585	Green	Not Green	82.72 [68.99, 90.57]	98.32 [98.85, 99.75]
	Ground Truth	4,017	1,065,568		
	AI	21,261	1,048,324		
Subgroup – Gender					
Male	Total: 202,807	Green	Not Green	51.20 [23.66, 79.25]	99.82 [99.66, 99.93]
	Ground Truth	832	201,975		
	AI	785	202,022		
Female	Total: 269,070	Green	Not Green	72.03 [45.29, 92.77]	99.19 [98.28, 99.88]
	Ground Truth	479	268,591		
	AI	2,524	266,546		
Unknown	Total: 1,448,732	Green	Not Green	71.63 [51.48, 85.63]	98.69 [98.06, 99.21]
	Ground Truth	4,762	1,443,970		
	AI	22,356	1,426,376		
Subgroup – Indications for Imaging					
Bleeding	Total: 1,090,684	Green	Not Green	82.15 [66.68, 90.27]	98.30 [97.47, 98.98]
	Ground Truth	3,687	1,086,997		
	AI	21,507	1,069,177		
No Bleeding	Total: 773,830	Green	Not Green	51.27 [30.44, 73.93]	99.62 [99.42, 99.79]
	Ground Truth	2,204	771,626		
	AI	4,091	769,739		
Unknown	Total: 56,095	Green	Not Green	12.64 [11.17, 100.00]	99.92 [99.87, 99.99]
	Ground Truth	182	55,913		
	AI	67	56,028		



	Total / Green / Not Green Frame Count			Sensitivity	Specificity
Subgroup – Finding of Bleeding					
Bleeding	Total: 1,303,755	Green	Not Green	68.14 [49.69, 82.04]	98.72 [98.04, 99.27]
	Ground Truth	5,571	1,298,184		
	AI	20,351	1,283,404		
No Bleeding	Total: 616,854	Green	Not Green	76.89 [54.30, 86.47]	99.20 [98.62, 99.67]
	Ground Truth	502	616,352		
	AI	5,314	611,540		

[1]. Analysis not conducted for the bowel prep poor subgroup as it comprised of one patient.

Table 7. Standalone Study Outcomes for the Suggested Landmark Feature for the Small Bowel (Frame-Level)

	Total / Yes (in Sm. Bowel) / No Frame Count			Sensitivity	Specificity
Overall	Total: 3,424,556	Yes	No	94.78 [91.96, 97.20]	90.97 [87.98, 93.60]
	Ground Truth	1,920,609	1,503,947		
	AI	1,956,030	1,468,526		
Subgroup – U.S. Region					
Midwest	Total: 682,449	Yes	No	96.54 [92.06, 99.67]	88.29 [80.83, 94.86]
	Ground Truth	398,846	283,603		
	AI	418,240	264,209		
Northeast	Total: 423,708	Yes	No	96.17 [87.67, 99.88]	92.62 [88.54, 96.25]
	Ground Truth	226,277	197,431		
	AI	232,185	191,523		
South	Total: 1,061,739	Yes	No	91.58 [85.58, 96.70]	89.96 [82.90, 95.10]
	Ground Truth	659,390	402,349		
	AI	644,300	417,439		
West	Total: 1,256,660	Yes	No	96.48 [92.46, 99.19]	92.33 [87.69, 96.16]
	Ground Truth	636,096	620,564		
	AI	661,305	595,355		
Subgroup – Bowel Prep					
Poor	Total: 36,396	Yes	No	N/A [1]	N/A [1]
	Ground Truth	12,271	24,125		
	AI	11,360	25,036		
Fair	Total: 1,087,793	Yes	No	90.30 [84.35, 95.31]	89.81 [82.57, 95.41]
	Ground Truth	681,621	406,172		
	AI	656,905	430,888		
Good	Total: 2,300,367	Yes	No	97.29 [94.60, 99.39]	91.21 [87.92, 94.08]
	Ground Truth	1,226,717	1,073,650		
	AI	1,287,765	1,012,602		

	Total / Yes (in Sm. Bowel) / No Frame Count			Sensitivity	Specificity
Subgroup – Age					
2-5	Total: 166,809	Yes	No	96.22 [88.45, 99.96]	98.29 [97.1, 100.00]
	Ground Truth	115,863	50,946		
	AI	112,355	54,454		
6-12	Total: 319,430	Yes	No	89.82 [76.10, 98.88]	91.62 [82.56, 99.55]
	Ground Truth	154,651	164,779		
	AI	152,715	166,715		
13-21	Total: 454,480	Yes	No	99.91 [99.81, 99.97]	90.93 [79.23, 98.26]
	Ground Truth	265,422	189,058		
	AI	282,315	172,165		
22-39	Total: 239,240	Yes	No	97.84 [92.67, 99.98]	94.48 [88.36, 99.40]
	Ground Truth	105,570	133,670		
	AI	110,675	128,565		
40-59	Total: 421,622	Yes	No	95.90 [89.50, 99.90]	93.53 [88.50, 97.31]
	Ground Truth	209,518	212,104		
	AI	214,635	206,987		
60+	Total: 1,822,975	Yes	No	93.54 [89.19, 97.11]	89.00 [84.38, 92.92]
	Ground Truth	1,069,585	753,390		
	AI	1,083,335	739,640		
Subgroup – Gender					
Male	Total: 366,793	Yes	No	93.46 [82.09, 99.72]	93.22 [87.05, 98.94]
	Ground Truth	202,807	163,986		
	AI	200,650	166,143		
Female	Total: 507,439	Yes	No	97.08 [93.80, 99.90]	95.64 [90.92, 99.10]
	Ground Truth	269,070	238,369		
	AI	271,610	235,829		
Unknown	Total: 2,550,324	Yes	No	94.53 [91.11, 97.40]	89.63 [85.78, 93.02]
	Ground Truth	1,448,732	1,101,592		
	AI	1,483,770	1,066,554		
Subgroup – Indications for Imaging					
Bleeding	Total: 1,975,457	Yes	No	94.52 [90.26, 97.82]	89.91 [85.75, 93.37]
	Ground Truth	1,090,684	884,773		
	AI	1,120,200	855,257		
No Bleeding	Total: 1,360,984	Yes	No	94.77 [90.70, 98.27]	94.69 [91.76, 97.31]
	Ground Truth	773,830	587,154		
	AI	764,550	596,434		
Unknown	Total: 88,115	Yes	No	99.73 [98.61, 100.00]	52.10 [23.30, 99.35]
	Ground Truth	56,095	32,020		

	Total / Yes (in Sm. Bowel) / No Frame Count			Sensitivity	Specificity
	AI	71,280	16,835		
Subgroup – Finding of Bleeding					
Bleeding	Total: 2,216,758	Yes	No	93.02 [89.01, 96.42]	89.92 [85.79, 93.48]
	Ground Truth	1,303,755	913,003		
	AI	1,304,720	912,038		
No Bleeding	Total: 1,207,798	Yes	No	98.49 [96.63, 99.78]	92.59 [88.21, 95.89]
	Ground Truth	616,854	590,944		
	AI	651,310	556,488		

[1]. Analysis not conducted for the bowel prep poor subgroup as it comprised of one patient.

Clinical Performance Evaluation (Reader Study)

A retrospective, multi-reader, multi-case (MRMC) study was conducted to evaluate the clinical performance of the proposed device. The study involved 15 independent, board-certified U.S. gastroenterologists reviewing capsule endoscopy videos collected from real-world clinical use. A split plot, crossover design was employed where subgroups of videos were allocated to “batches” of three readers each. Within each batch, each reader reviewed videos in both modalities (Conventional and AI-Assisted) on CapsoView in a randomized order, separated by a minimum washout period of four weeks to minimize memory bias.

The study aimed to demonstrate the clinical utility of the AI Highlights, Suggested Landmarks, and Green Detection Features, in reducing time to review small bowel capsule endoscopy videos. The co-primary endpoints of the study sought to demonstrate that the diagnostic accuracy (sensitivity) of endoscopists using the AI-assisted mode is non-inferior to conventional reading, and that the AI-assisted mode provides a statistically significant reduction in video reading time. Key additional endpoints evaluated other diagnostic metrics for reader performance between the two reading conditions, such as diagnostic yield.

The Reader Study included data from the same 111 patients in the Standalone Study. The analysis demonstrated that patient-level sensitivity with the CapsoView AI Software was non-inferior to conventional reading, with an observed sensitivity of 92.3% (95% CI: 87.8%, 96.7%) in the AI-assisted arm compared to 71.0% (95% CI: 59.2%, 82.7%) in the conventional arm. The difference in sensitivity was 21.3% (95% CI: 12.8%, 29.8%), which constituted non-inferiority (primary endpoint) and superiority (key secondary endpoint). The specificities of the AI-assisted and conventional arms were 26.4% (95% CI: 11.2%, 41.6%) and 56.2% (95% CI: 35.7%, 76.7%), a decrease comparable to that observed in prior studies. Furthermore, the study demonstrated a statistically significant reduction in the time required to review the capsule video, with the mean reading time decreasing from 45.7 minutes in the conventional arm to 34.4 minutes in the AI-assisted arm (difference: -11.3 minutes; 95% CI: -13.5 minutes, -9.0 minutes).

The study also demonstrated the superiority of the AI-assisted mode in diagnostic yield, meeting a key secondary endpoint. Diagnostic Yield increased from 63.3% (95% CI: 49.8%, 76.8%) in the conventional arm to 87.6% (95% CI: 81.2%, 93.9%) with AI assistance, a difference of 26.7%.



Subgroup analyses were performed for each endpoint by region (Midwest, West, Northeast, and South U.S., per U.S. Census Bureau regions), bowel preparation quality, patient age, patient gender, indications for imaging (bleeding related vs. not), and presence of blood in findings (found vs. not). The following presents the detailed subgroup analyses of the reader study results for both patient-level diagnostic performance and reading time, which include all primary and key secondary endpoints which were met by the study results.



Table 8. Summary of Reader Study Results – Diagnostic Performance – Patient Level

	Total / Positive / Negative Patient/Read (3/Video/Condition) Count			Sensitivity	Specificity	Diagnostic Yield
Overall	Total: 111 patients	Positive	Negative	Aided:	Aided:	Aided:
	Ground Truth (pt)	82	29	0.923	0.264	0.876
	AI Assisted (Reads)	291	42	[0.878, 0.967]	[0.112, 0.416]	[0.812, 0.939]
	Unassisted (Reads)	209	124	Unaided: 0.710 [0.592, 0.827] Difference: 0.213 [0.128, 0.298]	Unaided: 0.562 [0.357, 0.767] Difference: -0.298 [-0.454, -0.142]	Unaided: 0.633 [0.498, 0.768] Difference: 0.243 [0.160, 0.325]
Subgroup – U.S. Region						
Midwest	Total: 21 patients	Positive	Negative	Aided:	Aided:	Aided:
	Ground Truth (pt)	16	5	0.981	0.417	0.876
	AI Assisted (Reads)	55	8	[NE, NE]	[NE, NE]	[0.761, 0.990]
	Unassisted (Reads)	42	21	Unaided: 0.838 [NE, NE] Difference: 0.143 [NE, NE]	Unaided: 0.458 [NE, NE] Difference: -0.042 [NE, NE]	Unaided: 0.761 [0.589, 0.933] Difference: 0.115 [-0.025, 0.255]
Northeast	Total: 13 patients	Positive	Negative	Aided:	Aided:	Aided:
	Ground Truth (pt)	12	1	0.878	N/A ^[1]	0.878
	AI Assisted (Reads)	35	4	[NE, NE]	Unaided: N/A ^[1]	[0.760, 0.996]
	Unassisted (Reads)	28	11	Unaided: 0.711 [NE, NE] Difference: 0.167 [NE, NE]	Difference: N/A ^[1]	Unaided: 0.678 [0.448, 0.908] Difference: 0.200 [0.003, 0.397]
South	Total: 34 patients	Positive	Negative	Aided:	Aided:	Aided:
	Ground Truth (pt)	28	6	0.976	0.200	0.945
	AI Assisted (Reads)	97	5	[0.938, 1.000]	[NE, NE]	[0.875, 1.000]
	Unassisted (Reads)	71	31	Unaided: 0.717 [0.552, 0.882] Difference: 0.259 [0.118, 0.401]	Unaided: 0.600 [NE, NE] Difference: -0.400 [NE, NE]	Unaided: 0.661 [0.496, 0.825] Difference: 0.285 [0.150, 0.419]
West	Total: 43 patients	Positive	Negative	Aided:	Aided:	Aided:
	Ground Truth (pt)	26	17	0.842	0.250	0.814
	AI Assisted (Reads)	104	25	[0.693, 0.991]	[0.060, 0.440]	[0.696, 0.932]
	Unassisted (Reads)	68	61	Unaided: 0.625 [0.433, 0.817] Difference: 0.217 [0.064, 0.370]	Unaided: 0.606 [0.390, 0.821] Difference: -0.356 [-0.532, -0.179]	Unaided: 0.541 [0.353, 0.729] Difference: 0.273 [0.173, 0.373]
Subgroup – Bowel Prep ^[2]						
Fair	Total: 36 patients	Positive	Negative	Aided:	Aided:	Aided:
	Ground Truth (pt)	30	6	0.922	0.037	0.917
	AI Assisted (Reads)	101	7	[0.844, 1.000]	[NE, NE]	[0.840, 0.994]

	Total / Positive / Negative Patient/Read (3/Video/Condition) Count			Sensitivity	Specificity	Diagnostic Yield
	Unassisted (Reads)	72	36	Unaided: 0.690 [0.524, 0.856] Difference: 0.232 [0.065, 0.398]	Unaided: 0.278 [NE, NE] Difference: -0.241 [NE, NE]	Unaided: 0.679 [0.516, 0.843] Difference: 0.238 [0.074, 0.402]
Good	Total: 74 patients	Positive	Negative	Aided: 0.927 [0.871, 0.982]	Aided: 0.333 [NE, NE]	Aided: 0.840 [0.746, 0.935]
	Ground Truth (pt)	51	23	Unaided: 0.722 [0.609, 0.835] Difference: 0.205 [0.128, 0.281]	Unaided: 0.615 [NE, NE] Difference: -0.283 [NE, NE]	Unaided: 0.613 [0.468, 0.759] Difference: 0.227 [0.147, 0.306]
	AI Assisted (Reads)	188	34			
	Unassisted (Reads)	134	88			
Subgroup – Age						
2-5	Total: 5 patients	Positive	Negative	Aided: 1.000 [NE, NE] Unaided: 0.833 [NE, NE] Difference: 0.167 [NE, NE]	Aided: ¹ Unaided: ¹ Difference: ¹	Aided: 1.000 [NE, NE] Unaided: 0.833 [NE, NE] Difference: 0.167 [NE, NE]
	Ground Truth (pt)	5	0			
	AI Assisted (Reads)	15	0			
	Unassisted (Reads)	11	4			
6-12	Total: 12 patients	Positive	Negative	Aided: 0.889 [0.761, 1.000] Unaided: 0.815 [0.629, 1.000] Difference: 0.074 [-0.139, 0.288]	Aided: 0.167 [NE, NE] Unaided: 0.444 [NE, NE] Difference: -0.278 [NE, NE]	Aided: 0.892 [NE, NE] Unaided: 0.742 [NE, NE] Difference: 0.150 [NE, NE]
	Ground Truth (pt)	8	4			
	AI Assisted (Reads)	30	6			
	Unassisted (Reads)	25	11			
13-21	Total: 16 patients	Positive	Negative	Aided: 0.875 [NE, NE] Unaided: 0.646 [NE, NE] Difference: 0.229 [NE, NE]	Aided: 0.278 [NE, NE] Unaided: 0.542 [NE, NE] Difference: -0.264 [NE, NE]	Aided: 0.795 [0.649, 0.940] Unaided: 0.554 [0.291, 0.816] Difference: 0.241 [0.087, 0.395]
	Ground Truth (pt)	9	7			
	AI Assisted (Reads)	37	11			
	Unassisted (Reads)	24	24			
22-39	Total: 8 patients	Positive	Negative	Aided: 0.556 [NE, NE]	Aided: 0.389 [0.000, 0.789]	Aided: 0.688 [NE, NE]
	Ground Truth (pt)	3	5			
	AI Assisted (Reads)	14	10			

	Total / Positive / Negative Patient/Read (3/Video/Condition) Count			Sensitivity	Specificity	Diagnostic Yield
	Unassisted (Reads)	6	18	Unaided: 0.444 [NE, NE] Difference: 0.111 [NE, NE]	Unaided: 0.833 [0.444, 1.000] Difference: -0.444 [-0.788, -0.101]	Unaided: 0.417 [NE, NE] Difference: 0.271 [NE, NE]
40-59	Total: 13 patients	Positive	Negative	Aided: 0.944 [0.862, 1.000]	Aided: 0.000 [NE, NE]	Aided: 0.944 [0.862, 1.000]
	Ground Truth (pt)	11	2	Unaided: 0.569 [0.302, 0.837]	Unaided: 0.500 [NE, NE]	Unaided: 0.507 [0.230, 0.784]
	AI Assisted (Reads)	37	2	Difference: 0.375 [0.149, 0.601]	Difference: -0.500 [NE, NE]	Difference: 0.438 [0.192, 0.683]
	Unassisted (Reads)	21	18			
60+	Total: 57 patients	Positive	Negative	Aided: 0.965 [0.935, 0.995]	Aided: 0.206 [NE, NE]	Aided: 0.931 [0.876, 0.987]
	Ground Truth (pt)	46	11	Unaided: 0.774 [0.659, 0.888]	Unaided: 0.517 [NE, NE]	Unaided: 0.722 [0.591, 0.852]
	AI Assisted (Reads)	158	13	Difference: 0.191 [0.104, 0.278]	Difference: -0.311 [NE, NE]	Difference: 0.210 [0.118, 0.302]
	Unassisted (Reads)	122	49			
Subgroup – Gender						
Male	Total: 13 patients	Positive	Negative	Aided: 0.833 [NE, NE]	Aided: 0.556 [NE, NE]	Aided: 0.833 [NE, NE]
	Ground Truth (pt)	9	4	Unaided: 0.750 [NE, NE]	Unaided: 0.778 [NE, NE]	Unaided: 0.650 [NE, NE]
	AI Assisted (Reads)	31	8	Difference: 0.083 [NE, NE]	Difference: -0.222 [NE, NE]	Difference: 0.183 [NE, NE]
	Unassisted (Reads)	22	17			
Female	Total: 18 patients	Positive	Negative	Aided: 0.933 [NE, NE]	Aided: 0.233 [NE, NE]	Aided: 0.833 [NE, NE]
	Ground Truth (pt)	11	7	Unaided: 0.692 [NE, NE]	Unaided: 0.667 [NE, NE]	Unaided: 0.489 [NE, NE]
	AI Assisted (Reads)	46	8	Difference: 0.242 [NE, NE]	Difference: -0.433 [NE, NE]	Difference: 0.344 [NE, NE]
	Unassisted (Reads)	31	23			
Unknown	Total: 80 patients	Positive	Negative	Aided: 0.943 [0.896, 0.989]	Aided: 0.244 [0.086, 0.403]	Aided: 0.898 [0.828, 0.967]
	Ground Truth (pt)	62	18			
	AI Assisted (Reads)	214	26			

	Total / Positive / Negative Patient/Read (3/Video/Condition) Count			Sensitivity	Specificity	Diagnostic Yield
	Unassisted (Reads)	156	84	Unaided: 0.730 [0.611, 0.850] Difference: 0.212 [0.123, 0.302]	Unaided: 0.511 [0.243, 0.779] Difference: -0.267 [-0.532, -0.002]	Unaided: 0.666 [0.534, 0.798] Difference: 0.232 [0.145, 0.319]
Subgroup – Indications for Imaging ^[3]						
Bleeding	Total: 63 patients	Positive	Negative	Aided: 0.947	Aided: 0.239	Aided: 0.904
	Ground Truth (pt)	50	13	[0.901, 0.993]	[0.069, 0.409]	[0.834, 0.975]
	AI Assisted (Reads)	170	19			
	Unassisted (Reads)	123	66	Unaided: 0.737 [0.610, 0.864] Difference: 0.210 [0.119, 0.301]	Unaided: 0.583 [0.316, 0.851] Difference: -0.344 [-0.597, -0.092]	Unaided: 0.671 [0.534, 0.808] Difference: 0.233 [0.140, 0.325]
No Bleeding	Total: 45 patients	Positive	Negative	Aided: 0.899	Aided: 0.389	Aided: 0.843
	Ground Truth (pt)	31	14	[0.809, 0.989]	[NE, NE]	[0.724, 0.961]
	AI Assisted (Reads)	115	20			
	Unassisted (Reads)	82	53	Unaided: 0.656 [0.469, 0.844] Difference: 0.243 [0.044, 0.442]	Unaided: 0.678 [NE, NE] Difference: -0.289 [NE, NE]	Unaided: 0.571 [0.382, 0.760] Difference: 0.272 [0.128, 0.416]
Unknown	Total: 3 patients	Positive	Negative	Aided: ³	Aided: ³	Aided: ³
	Ground Truth (pt)	1	2	Unaided: ³	Unaided: ³	Unaided: ³
	AI Assisted (Reads)	6	3	Difference: ³	Difference: ³	Difference: ³
	Unassisted (Reads)	4	5			
Subgroup – Finding of Bleeding						
Bleeding	Total: 72 patients	Positive	Negative	Aided: 0.941	Aided: 0.150	Aided: 0.928
	Ground Truth (pt)	60	12	[0.900, 0.982]	[NE, NE]	[0.877, 0.978]
	AI Assisted (Reads)	201	15			
	Unassisted (Reads)	162	54	Unaided: 0.770 [0.660, 0.879] Difference: 0.171 [0.083, 0.259]	Unaided: 0.506 [NE, NE] Difference: -0.356 [NE, NE]	Unaided: 0.729 [0.611, 0.846] Difference: 0.199 [0.108, 0.290]
No Bleeding	Total: 39 patients	Positive	Negative	Aided: 0.892	Aided: 0.340	Aided: 0.785
	Ground Truth (pt)	22	17	[NE, NE]	[NE, NE]	[0.643, 0.927]
	AI Assisted (Reads)	90	27			
	Unassisted (Reads)	47	70	Unaided: 0.531 [NE, NE] Difference: 0.361 [NE, NE]	Unaided: 0.604 [NE, NE] Difference: -0.264 [NE, NE]	Unaided: 0.474 [0.300, 0.648] Difference: 0.311 [0.193, 0.429]



	Total / Positive / Negative Patient/Read (3/Video/Condition) Count	Sensitivity	Specificity	Diagnostic Yield
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[1]: Insufficient number for calculation.

[2]: Analysis not conducted for the bowel prep poor subgroup as it comprised of one patient.

[3] Analysis not conducted for the unknown indication as it comprises of less than 5 patients.

Table 9. Summary of Reading Time Analysis – Patient Level

	Small Bowel Reading Time [minutes]		
Overall	Total: 111 patients	Read Count (3/pt/condition)	Aided: 34.393 [18.013, 50.773]
	AI Assisted (Reads)	329	Unaided: 45.687 [29.306, 62.067]
	Unassisted (Reads)	331	Difference: -11.294 [-13.545, -9.043]
Subgroup – U.S. Region			
Midwest	Total: 21 patients	Read Count (3/pt/condition)	Aided: 37.244 [17.831, 56.658]
	AI Assisted (Reads)	63	Unaided: 50.879 [31.465, 70.293]
	Unassisted (Reads)	63	Difference: -13.635 [-19.439, -7.831]
Northeast	Total: 13 patients	Read Count (3/pt/condition)	Aided: 32.368 [20.198, 44.538]
	AI Assisted (Reads)	38	Unaided: 44.684 [32.514, 56.853]
	Unassisted (Reads)	38	Difference: -12.316 [-18.366, -6.266]
South	Total: 34 patients	Read Count (3/pt/condition)	Aided: 36.022 [20.613, 51.431]
	AI Assisted (Reads)	101	Unaided: 47.717 [32.305, 63.129]
	Unassisted (Reads)	102	Difference: -11.695 [-15.994, -7.395]
West	Total: 43 patients	Read Count (3/pt/condition)	Aided: 32.160 [15.191, 49.129]
	AI Assisted (Reads)	127	Unaided: 41.734 [24.765, 58.704]
	Unassisted (Reads)	128	Difference: -9.574 [-13.036, -6.112]
Subgroup – Bowel Prep ^[1]			
Fair	Total: 36 patients	Read Count (3/pt/condition)	Aided: 41.224 [23.043, 59.405]
	AI Assisted (Reads)	107	Unaided: 46.193 [28.010, 64.376]
	Unassisted (Reads)	108	Difference: -4.969 [-8.803, -1.135]
Poor	Total: 1 patient	Read Count (3/pt/condition)	Aided: N/A ^[1]
	AI Assisted (Reads)	3	Unaided: N/A ^[1]
	Unassisted (Reads)	3	Difference: N/A ^[1]
Good	Total: 74 patients	Read Count (3/pt/condition)	Aided: 30.420 [14.593, 46.247]
	AI Assisted (Reads)	219	Unaided: 45.258 [29.431, 61.084]
	Unassisted (Reads)	220	Difference: -14.837 [-17.582, -12.093]
Subgroup – Age			
2-5	Total: 5 patients	Read Count (3/pt/condition)	Aided: 26.116 [-67.887, 120.119]
	AI Assisted (Reads)	14	Unaided: 36.751 [-63.543, 137.044]
	Unassisted (Reads)	15	Difference: -10.635 [-16.584, -4.687]
6-12	Total: 12 patients	Read Count (3/pt/condition)	Aided: 37.730 [13.860, 61.601]
	AI Assisted (Reads)	36	Unaided: 40.369 [16.499, 64.240]
	Unassisted (Reads)	36	Difference: -2.639 [-9.028, 3.750]
13-21	Total: 16 patients	Read Count (3/pt/condition)	Aided: 31.701 [8.017, 55.385]
	AI Assisted (Reads)	47	Unaided: 45.557 [21.899, 69.216]
	Unassisted (Reads)	47	Difference: -13.856 [-19.317, -8.396]
22-39	Total: 8 patients	Read Count (3/pt/condition)	Aided: 26.516 [4.864, 48.167]
	AI Assisted (Reads)	24	Unaided: 40.182 [18.531, 61.834]
	Unassisted (Reads)	24	Difference: -13.667 [-22.403, -4.930]
40-59	Total: 13 patients	Read Count (3/pt/condition)	Aided: 41.919 [21.102, 62.737]
	AI Assisted (Reads)	39	Unaided: 47.047 [26.230, 67.865]
	Unassisted (Reads)	39	Difference: -5.128 [-12.588, 2.331]
60+	Total: 57 patients	Read Count (3/pt/condition)	Aided: 35.224 [19.875, 50.572]



Small Bowel Reading Time [minutes]			
	AI Assisted (Reads)	169	Unaided: 48.831 [33.481, 64.181]
	Unassisted (Reads)	170	Difference: -13.608 [-16.842, -10.373]
Subgroup – Gender			
Male	Total: 13 patients	Read Count (3/pt/condition)	Aided: 36.204 [19.564, 52.845]
	AI Assisted (Reads)	37	Unaided: 42.906 [26.248, 59.564]
	Unassisted (Reads)	39	Difference: -6.702 [-13.564, 0.161]
Female	Total: 18 patients	Read Count (3/pt/condition)	Aided: 32.180 [12.945, 51.416]
	AI Assisted (Reads)	54	Unaided: 44.336 [25.109, 63.564]
	Unassisted (Reads)	53	Difference: -12.156 [-17.294, -7.019]
Unknown	Total: 80 patients	Read Count (3/pt/condition)	Aided: 35.082 [19.506, 50.658]
	AI Assisted (Reads)	238	Unaided: 47.013 [31.436, 62.590]
	Unassisted (Reads)	239	Difference: -11.931 [-14.602, -9.261]
Subgroup – Indications for Imaging^[2]			
Bleeding	Total: 63 patients	Read Count (3/pt/condition)	Aided: 34.739 [18.210, 51.268]
	AI Assisted (Reads)	187	Unaided: 47.235 [30.704, 63.765]
	Unassisted (Reads)	188	Difference: -12.496 [-15.656, -9.335]
No Bleeding	Total: 45 patients	Read Count (3/pt/condition)	Aided: 32.866 [18.410, 47.321]
	AI Assisted (Reads)	133	Unaided: 42.120 [27.665, 56.576]
	Unassisted (Reads)	134	Difference: -9.254 [-12.567, -5.942]
Unknown	Total: 3 patients	Read Count (3/pt/condition)	Aided: N/A ^[1]
	AI Assisted (Reads)	9	Unaided: N/A ^[1]
	Unassisted (Reads)	9	Difference: N/A ^[1]
Subgroup – Finding of Bleeding			
Bleeding	Total: 72 patients	Read Count (3/pt/condition)	Aided: 37.785 [20.268, 55.302]
	AI Assisted (Reads)	213	Unaided: 45.673 [28.156, 63.190]
	Unassisted (Reads)	214	Difference: -7.888 [-10.645, -5.131]
No Bleeding	Total: 39 patients	Read Count (3/pt/condition)	Aided: 29.104 [13.486, 44.722]
	AI Assisted (Reads)	116	Unaided: 46.603 [30.984, 62.222]
	Unassisted (Reads)	117	Difference: -17.499 [-21.315, -13.683]

[1]: Analysis not conducted for the bowel prep poor subgroup as it comprised of one patient.

[2] Analysis not conducted for the unknown indication as it comprises of less than 5 patients.

Conclusion

The results of the standalone and clinical performance studies support that the proposed device functions as intended, and that use of the device achieves decreased small bowel capsule endoscopy reading time relative to “unassisted” review.

CapsoVision believes that the collective results of non-clinical and clinical performance testing support the safety and performance of the proposed device for its Indications for Use, and that that the proposed device is at least as safe and as effective as the predicate device for the same Intended Use.