March 12, 2026

DigestAID - Artificial Intelligence Development, S.A.
Miguel Mascarenhas
CEO
Rua Particular Carlos Fontes, 117, São Cosme
Gondomar, Porto 4420-249
Portugal

Re: K250655
Trade/Device Name: Deep Capsule® (Deep Capsule US)
Regulation Number: 21 CFR 876.1540
Regulation Name: Gastrointestinal Capsule Endoscopy Analysis Software Device
Regulatory Class: Class II
Product Code: QZF
Dated: March 10, 2026
Received: March 10, 2026

Dear Miguel Mascarenhas:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality 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
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K250655

Device Name
Deep Capsule®

Indications for Use *(Describe)*
Deep Capsule® is an artificial intelligence (AI) assisted reading tool designed to aid small bowel capsule endoscopy reviewers in decreasing the time to review capsule endoscopy images for adult patients in whom the capsule endoscopy images were obtained for suspected small bowel bleeding. The clinician is responsible for conducting their own assessment of the findings of the AI-assisted reading through review of the entire video, as clinically appropriate. This tool is not intended to replace clinical decision-making.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

807.92(a)(1) – Submitter Information	
Date	08-August-2025
Submitter	DigestAID - Artificial Intelligence Development SA
Primary Contact Person	Dr. Miguel Mascarenhas CEO DigestAID Email: miguel.mascarenhas@digestaid.health Ph: +351 915 065 586
Secondary Contact Person	Dr. Hélder Cardoso CMO DigestAID Email: helder.cardoso@digestaid.health Ph: +351 916 022 457
807.92(a)(2) – Device Information	
Device Trade Name	Deep Capsule®
Common/Usual Name	Gastrointestinal capsule endoscopy analysis software device
Regulation Name	Gastrointestinal capsule endoscopy analysis software device
Regulation Number	876.1540
Regulation Class	Class II
Product Code	QZF
Review Panel	Gastroenterology/Urology
807.92(a)(3) – Predicate Device	
De Novo Number	**DEN230027**
Manufacturer	Ankon Technologies Co., Ltd
CFR	21 CFR § 876.1540
Classification Product Code	QZF
Predicate Device(s)	NaviCam ProScan

Indications for Use

The Deep Capsule® is indicated as follows:

Deep Capsule® is an artificial intelligence (AI) assisted reading tool designed to aid small bowel capsule endoscopy reviewers in decreasing the time to review capsule endoscopy images for adult patients in whom the capsule endoscopy images were obtained for suspected small bowel bleeding. The clinician is responsible for conducting their own assessment of the findings of the AI-assisted reading through review of the entire video, as clinically appropriate. This tool is not intended to replace clinical decision-making.

Limitations

Deep Capsule® is not intended to be used as a stand-alone diagnostic device or replace clinical decision-making. The device is intended to assist qualified healthcare professionals in reviewing small bowel capsule endoscopy videos.

Deep Capsule® should only be use with compatible small bowel capsule endoscopy systems as specified in the labeling.

Deep Capsule® is not intended for autonomous diagnostic use. The clinician is responsible for making the final clinical diagnosis.

A negative or normal result determined by Deep Capsule® alone does not exclude the presence of small bowel disease (false negative). Similarly, a positive or abnormal result does not automatically confirm the presence of small bowel disease (false positive). The clinician should always carefully review the complete capsule endoscopy video in accordance with standard clinical practice. If clinical symptoms persist, further evaluation should be performed.

Deep Capsule® is not intended to characterize lesions in a manner that would replace biopsy sampling or other characterization tools.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS, AND CONTRAINDICATIONS.

Device Description

Deep Capsule® is an artificial intelligence (AI) assisted reading tool designed to aid small bowel capsule endoscopy reviewers (SBCapER) in decreasing the time to review capsule endoscopy images for adult patients in whom the capsule endoscopy images were obtained for suspected small bowel bleeding.

Deep Capsule® is capable of detecting small bowel lesions, without differentiating them. The detection of lesions by Deep Capsule® is insufficient to achieve a direct diagnosis, which is dependent on the clinical integration of the different findings. Deep Capsule® should be integrated into this multifactorial and complex context, both in the diagnostic workup or in the patient follow-up.

In summary, although the Deep Capsule® detects small bowel lesions, it acts only as a support to the clinical decision. The ultimate diagnosis will always be given by the small bowel capsule endoscopy reviewers ("human in the loop").

It is important to note that Deep Capsule® also provides in the findings count as a non-AI software output, and user inputs that are inserted and edited by SBCapERs, including CapE device model, patient exam priority category, procedure date, responsible physician, clinical indication and medical notes.

Deep Capsule® software includes a main algorithm as illustrated in Figure 1:

• Small bowel lesion detection, which includes the small bowel lesion image analysis algorithm designed to automatically identify and localize potential small bowel lesions in capsule endoscopy images. Suspected findings are selected automatically from the video frames as illustrated in Figure 1 below, with the active video displayed on the left side of the user interface. On the right side, AI-selected frames are presented as a structured gallery of thumbnails, allowing the reviewer to efficiently navigate through suspected findings. The interface also provides exam details, frame indexing, clinical indication, findings count, and medical notes to support structured review.

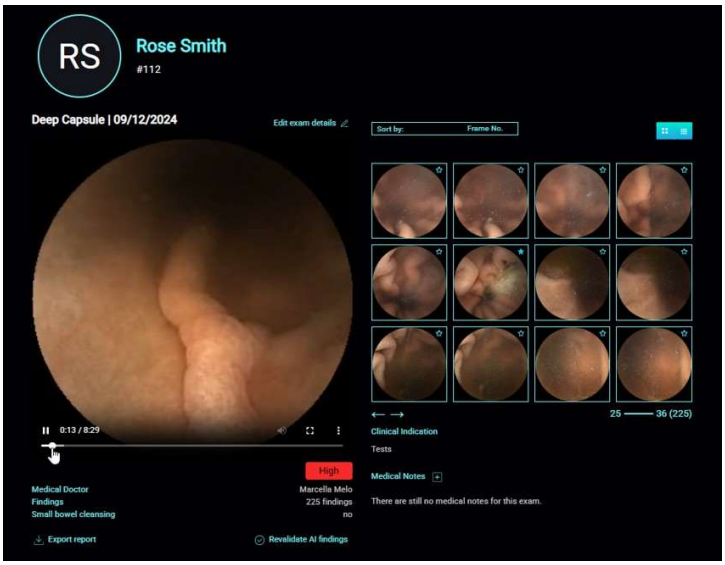


Figure 1: Lesion Recognition

The Deep Capsule® detection algorithm is based on convolutional neural networks using different deep learning models.

Table 1: Comparison of Indications for Use and Technological Characteristics

Characteristic	Subject Device	Predicate Device	Explanation of Difference
Device name	Deep Capsule®	NaviCam ProScan	N/A
FDA Clearance	K250655	DEN230027	N/A
Classification Name	Gastrointestinal capsule endoscopy analysis software device	Gastrointestinal capsule endoscopy analysis software device	Same
FDA Reg #	21 CFR 876.1540	21 CFR 876.1540	Same
FDA Product Code	QZF	QZF	Same
Classification	Class II	Class II	Same
Indications for Use	Deep Capsule® is an artificial intelligent (AI) assisted reading tool designed to aid small bowel capsule endoscopy reviewers in decreasing the time to review capsule endoscopy images for adult patients in whom the capsule endoscopy images were obtained for suspected small bowel bleeding. The clinician is responsible for conducting their own assessment of the findings of the AI-assisted reading through a review of the entire video, as clinically appropriate. This tool is not intended to replace clinical decision-making.	NaviCam ProScan is an artificial intelligent (AI) assisted reading tool designed to aid small bowel capsule endoscopy reviewers in decreasing the time to review capsule endoscopy images for adult patients in whom the capsule endoscopy images were obtained for suspected small bowel bleeding. The clinician is responsible for conducting their own assessment of the findings of the AI-assisted reading through review of the entire video, as clinically appropriate. ProScan also assists small bowel capsule endoscopy reviewers in identifying the digestive tract location (oral cavity and beyond, esophagus, stomach,	Similar - Both devices are computer-aided detection (CADe) tools designed to assist endoscopy reviewers in decreasing the time to review capsule endoscopy images for adult patients in whom the capsule endoscopy images were obtained for suspected small bowel bleeding. None of the technologies are intended to replace clinical decision-making. The only difference is that NaviCam ProScan also assists small bowel

Characteristic	Subject Device	Predicate Device	Explanation of Difference
		small bowel) of the image in adults. This tool is not intended to replace clinical decision-making.	capsule endoscopy reviewers in identifying the digestive tract location (oral cavity and beyond, esophagus, stomach, small bowel) of the image in adults, and Deep Capsule® does not.
Anatomical site	Small bowel	Small bowel	Same
Function	CADe	CADe	Same
Analysis	Capsule endoscopy images review	Capsule endoscopy images review	Same
Target Population	Adult patients with suspicion of small bowel bleeding.	Adult patients with suspicion of small bowel bleeding.	Same
Targeted Disease	Small bowel bleeding	Small bowel bleeding	Same
Type of Procedure	Capsule endoscopy	Capsule endoscopy	Same
Technological Characteristics	Deep Capsule® is a SaMD designed to detect potential small bowel lesions.	NaviCam ProScan is a SaMD designed to detect potential small bowel lesions and digestive tract structures location identification.	Similar - Both devices are SaMD to detect potential small bowel lesions. The only difference is that NaviCam ProScan has an extra feature for digestive tract location identification, while Deep Capsule® does not.

Characteristic	Subject Device	Predicate Device	Explanation of Difference
Software Algorithm	Deep Capsule® uses an artificial intelligence-based algorithm to perform potential small bowel lesions detection.	NaviCam ProScan uses an artificial intelligence-based algorithm to detect potential small bowel lesions and identify digestive tract locations.	Similar - Both devices use an artificial intelligence-based algorithm to perform the detection of lesions in the small bowel. The only difference is that NaviCam ProScan also identifies digestive tract location, while Deep Capsule® does not.
Explainable AI Strategy	Is based on potential small bowel lesion frames detection/selection.	Is based on potential small bowel lesions frames detection/ selection. It also gives digestive tract structure locations.	Similar - Both devices are based on an artificial intelligence algorithm that selects potential lesion frames in the small bowel. The only difference is that NaviCam ProScan AI also identifies digestive tract location, while Deep Capsule® does not.
Device AI Output	Deep Capsule® generates a report with the potential small bowel lesion frames selected by the small bowel capsule endoscopy reviewer.	NaviCam ProScan generates a report with the potential small bowel lesion frames selected by the small bowel capsule endoscopy reviewer. It also gives digestive tract structure locations.	Similar - generates a report with the potential small bowel lesion frames selected by the small bowel capsule endoscopy reviewer. The only difference is that NaviCam ProScan also identifies the location of digestive tract structures, while Deep Capsule® does not.

Characteristic	Subject Device	Predicate Device	Explanation of Difference
Device non-AI Output	Finding count Patient Exam Priority	Not applicable	The NaviCam ProScan is an AI tool integrated into ESView, the image review software used in the NaviCam SB System. The non-AI outputs are not part of the NaviCam ProScan tool.

Summary of Non-Clinical Tests/Bench Studies

Software/Cybersecurity

Deep Capsule® 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. Deep Capsule® 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. This testing is not part of the AI performance evaluation.

Regarding the 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.

PERFORMANCE TESTING – BENCH – STANDALONE PERFORMANCE

The optimization, training, and validation of the Deep Capsule® was performed in several phases, as summarized below.

Algorithm Training

In the training phase, Deep Capsule® was trained to recognize abnormal small bowel capsule endoscopy images for lesion detection. A dataset of 1,133 patients who underwent small bowel capsule endoscopy was collected from multiple Capsule Endoscopy System (PillCam™ SB3, PillCam™ Crohn, PillCam™ SB1, PillCam™ Colon2, OMOM® HD System, Olympus ENDOCAPSULE 10 (EC-10)) obtained from 2 clinical institutions in Portugal. The dataset included 321,357 expert-labeled images drawn from full-length capsule endoscopy examinations.

Of those 1,133 patients, the dataset was split so that:

- 861 patients (76.0%) were used for training the lesion detection function; and

- 272 patients (24.0%) were used for internal testing of the lesion detection function (see Standalone Algorithm Testing with full demographics tables 2 and 3) .

Table 2: Lesion Detection Function.

	Training (No. of subjects = 861)	**Model** (No. of subjects = 272)
Age:		
Mean Age, years (SDV)	53.36 (17.90)	58.11 (18.88)
Age range	18–91	18–91
Sex:		
Male	416	119
Female	445	153
Race/Ethnicity:		
White or Caucasian	861	272
Black or African American	0	0
Hispanic or Latino	0	0
Asian	0	0
Native Hawaiian or Other Pacific Islander	0	0
Other / Not Reported	0	0

Table 3: Demographics of standalone performance dataset.

	Model Dataset	**Model Training Set**	**Model Test Set**
Images			
Images, N (%)	321357 (100%)	219555 (68.3%)	101802 (31.7%)
	Images per device (count)		
PillCam™ SB3	229467 (71.41%)	154200 (70.23%)	75267 (73.93%)
PillCam™ Crohn	71164 (22.14%)	53027 (24.15%)	18137 (17.82%)
OMOM® HD	20619 (6.42%)	12221 (5.57%)	8398 (8.25%)
Olympus EC-10®	45 (0.01%)	45 (0.02%)	-- (0%)
PillCam™ Colon2	35 (0.01%)	35 (0.02%)	-- (0%)
PillCam™ SB1	20 (0.01%)	20 (0.01%)	-- (0%)
Subjects			
Exams, N (%)	1133 (100%)	861 (75.9%)	272 (24.1%)
Male, N (%)	535 (47%)	416 (48%)	119 (44%)
Female, N (%)	598 (53%)	445 (52%)	153 (56%)

Mean Age, years (SDV)	54.87 (18.35)	53.36 (17.90)	58.11 (18.88)
Subjects per device (count)			
PillCam™ SB3	888 (78.24%)	676 (78.3%)	212 (77.9%)
PillCam™ Crohn	82 (7.22%)	82 (9.5%)	20 (7.35%)
OMOM® HD	137 (12.07%)	97 (11.2%)	40 (14.7%)
Olympus EC-10®	1 (0.09%)	1 (0.1%)	-- (0%)
PillCam™ Colon2	3 (0.26%)	3 (0.4%)	-- (0%)
PillCam™ SB1	2 (0.18%)	2 (0.23%)	-- (0%)
Subjects per clinical indication (count)			
NA	411 (36.27%)	305 (35.42%)	106 (38.97%)
Anemia	281 (24.80%)	225 (26.13%)	56 (20.59%)
Crohn"s Disease Staging	164 (14.47%)	126 (14.63%)	38 (13.97%)
Crohn"s Disease Diagnose	133 (11.74%)	100 (11.61%)	33 (12.13%)
OGIB	74 (6.53%)	50 (5.81%)	24 (8.82%)
FAP	26 (2.29%)	22 (2.56%)	4 (1.47%)
Other Polyposis	12 (1.06%)	9 (1.04%)	3 (1.10%)
NET	8 (0.71%)	7 (0.81%)	1 (0.37%)
Peutz-Jeghers Syndrome	7 (0.62%)	4 (0.46%)	3 (1.10%)
Common Variable Immunodefency	6 (0.53%)	4 (0.46%)	2 (0.74%)
Celiac Disease	3 (0.26%)	3 (0.35%)	-- (0%)
Imagiological Anormality	3 (0.26%)	3 (0.35%)	-- (0%)
Chronic Diarrhea	2 (0.18%)	2 (0.23%)	-- (0%)
HNPCC	2 (0.18%)	-- (0%)	2 (0.74%)
CRC Screening	1 (0.08%)	1 (0.12%)	-- (0%)
Subjects per Race/Ethnicity			
White or Caucasian	1133 (100%)	861 (100%)	272 (100%)
Black or African American	-- (0%)	-- (0%)	-- (0%)
Hispanic or Latino	-- (0%)	-- (0%)	-- (0%)
Asian	-- (0%)	-- (0%)	-- (0%)
Native Hawaiian or other Pacific Islander	-- (0%)	-- (0%)	-- (0%)

Note: Additionally, center-based stratification is not presented separately, as the training dataset was derived from two Portuguese centers: Centro Hospitalar Universitário São João (CHUSJ), Porto, Portugal (n = 1008 patients), and ManopH – Laboratório de Endoscopia e Motilidade Digestiva, Lda., Vila Nova de Gaia, Portugal (n = 127 patients).

Image Labeling Process

Images included in the dataset were labeled by expert readers following a structured annotation process.

Capsule Compatibility and Acquisition System Transparency

The table below summarizes capsule system inclusion across development and validation phases:

Table 4: Standalone Performance, and Clinical Validation by Capsule Model

Capsule Model	Standalone Performance	Clinical Validation
PillCam™ SB3	Yes	Yes (n=307)
PillCam™ SB2	No standalone	Limited (n=2)
ENDOCAPSULE 10	No standalone	Yes (n=21)
OMOM® HD	Yes (internal)	No

Performance metrics for certain capsule systems (e.g., PillCam™ SB2) are based on limited sample sizes and should be interpreted accordingly. OMOM® HD was included during internal development and standalone robustness testing but is not part of the U.S. compatibility claims.

This structured reporting ensures transparency regarding tested hardware and associated subgroup analyses, consistent with 21 CFR 876.1540 Special Control 5(ii).

Standalone Algorithm Testing

1. **Lesion detection function**

Following the training phase, the performance of the Deep Capsule® to correctly recognize small bowel images with lesions was tested. For this purpose, 272 patients from the dataset described in Table 3 were selected for testing, with patient-level results provided in Tables 5 and 6 below. From that same dataset, normal and abnormal small bowel capsule endoscopy images were used to test the algorithm, with image-level results provided in Tables 7 and 8.

a. Patient-Level Analysis

Table 5: Patient-level Analysis Results.

	Expert Reading		Sensitivity (95% CI)	Specificity (95% CI)	AUC
Deep Capsule Prediction	Lesion	Normal	**0.958** (0.927, 0.979)	**0.750** (0.349, 0.968)	**0.966** (0.939 - 0.993)
Lesion	253	2			
Normal	11	6			

Patient-level sensitivity and specificity were determined to be 95.8% (95% CI: 92.7%-97.9%) and 75% (95%CI: 34.9%-96.8%), respectively.

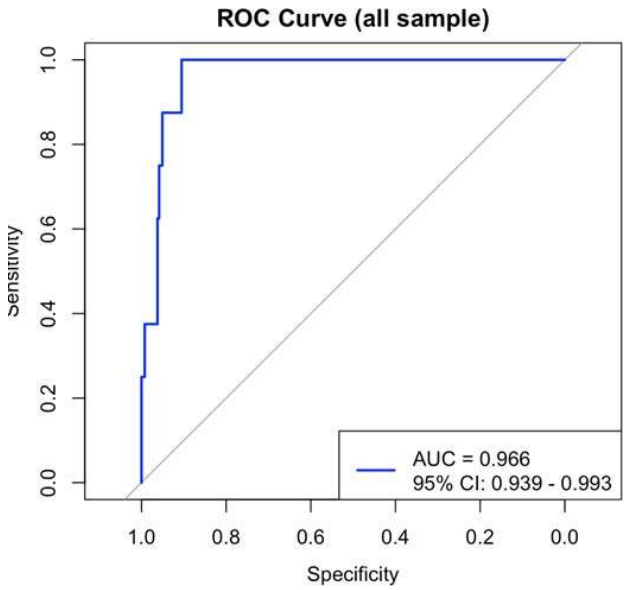


Figure 2: Patient-Level ROC and AUC Analysis.

Results of subgroup analyses based on gender, age range, collection site, device and clinical indication are presented in Table 6 and Figure 3 below.

Table 6: Patient-level Subgroup Analysis Results.

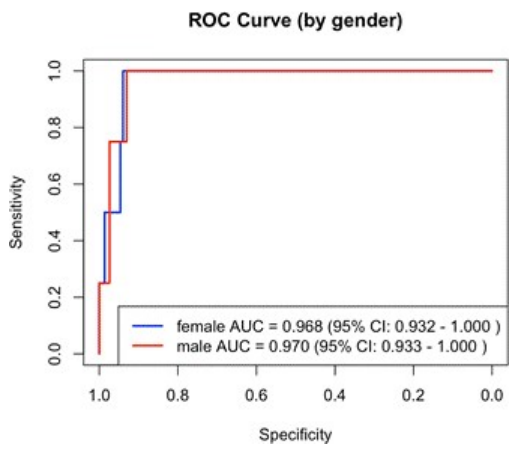
	Deep Capsule Prediction	Expert Reading		Sensitivity (95% CI)	Specificity (95% CI)	AUC
		Lesion	Normal			
PillCam™ SB3	Lesion	204	2	**0.981** (0.951 - 0.995)	**0.333** (0.008 - 0.906)	**0.965** (0.927 - 1.000)
	Normal	4	1			
PillCam™ Crohn	Lesion	16	0	**0.842** (0.604 - 0.966)	**1.000** (0.025 - 1.000)	**0.842** (NA - NA)
	Normal	3	1			
OMOM® HD	Lesion	33	0	**0.892** (0.746 - 0.970)	**1.000** (0.398 - 1.000)	**0.973** (0.914 - 1.000)
	Normal	4	4			

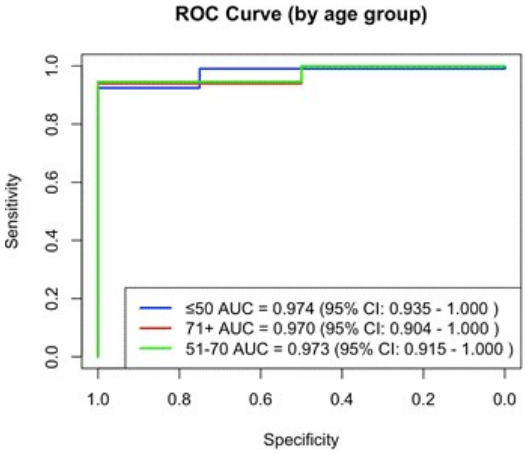
	Deep Capsule Prediction	Expert Reading		Sensitivity (95% CI)	Specificity (95% CI)	AUC
		Lesion	Normal			
Male	Lesion	112	1	**0.974** (0.926, 0.995)	**0.750** (0.194 - 0.994)	**0.970** (0.933 - 1.000)
	Normal	3	3			
Female	Lesion	141	1	**0.946** (0.897 - 0.977)	**0.750** (0.194 - 0.994)	**0.968** (0.932 - 1.000)
	Normal	8	3			
≤ 50 years old	Lesion	105	2	**0.991** (0.949, 1.000)	**0.500** (0.068 - 0.932)	**0.974** (0.935 - 1.000)
	Normal	1	2			
51-70 years old	Lesion	87	0	**0.946** (0.878 - 0.982)	**1.000** (0.158 - 1.000)	**0.973** (0.915 - 1.000)
	Normal	5	2			
71+ years old	Lesion	61	0	**0.924** (0.832 - 0.975)	**1.000** (0.158 - 1.000)	**0.970** (0.904 - 1.000)
	Normal	5	2			
CHUSJ (1)	Lesion	224	2	**0.970** (0.939, 0.988)	**0.500** (0.068 - 0.932)	**0.957** (0.921 - 0.993)
	Normal	7	2			
ManopH (2)	Lesion	29	0	**0.879** (0.718 - 0.966)	**1.000** (0.398 - 1.000)	**0.970** (0.904 - 1.000)
	Normal	4	4			
NA	Lesion	93	1	**0.939** (0.874 - 0.972)	**0.857** (0.487 - 0.974)	**0.962** (0.925 - 1.000)
	Normal	6	6			
Anemia	Lesion	54	0	**0.964** (0.879 - 0.990)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	2	0			
Crohn"s Disease Diagnose	Lesion	33	0	**1.000** (0.896 - 1.000)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	0	0			
OGIB	Lesion	22	0	**0.917** (0.742 - 0.977)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	2	0			
Crohn"s Disease Staging	Lesion	38	0	**1.000** (0.908 - 1.000)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	0	0			
FAP	Lesion	3	1	**1.000** (0.439 - 1.000)	**0.000** (0.000 - 0.793)	**NA** (NA - NA)
	Normal	0	0			
HNPCC	Lesion	2	0	**1.000** (0.342 - 1.000)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	0	0			
Other Polyposis	Lesion	2	0	**0.667** (0.208 - 0.939)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	1	0			
Common	Lesion	2	0	**1.000**	**NA**	**NA**

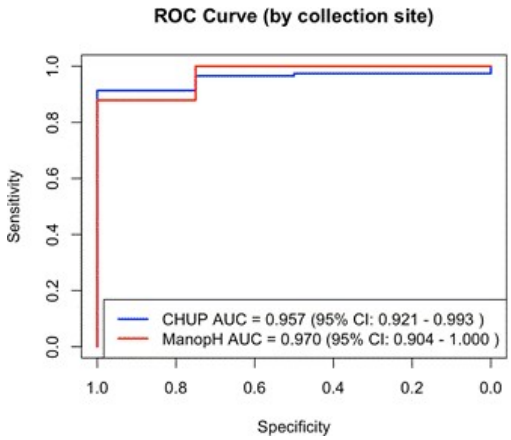
	Deep Capsule Prediction	Expert Reading		Sensitivity (95% CI)	Specificity (95% CI)	AUC
		Lesion	Normal			
Variable Immunodefency	Normal	0	0	(0.342 - 1.000)	(NA - NA)	(NA - NA)
Peutz-Jeghers Syndrome	Lesion	3	0	1.000 (0.439 - 1.000)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	0	0			
NET	Lesion	1	0	1.000 (0.207 - 1.000)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	0	0			

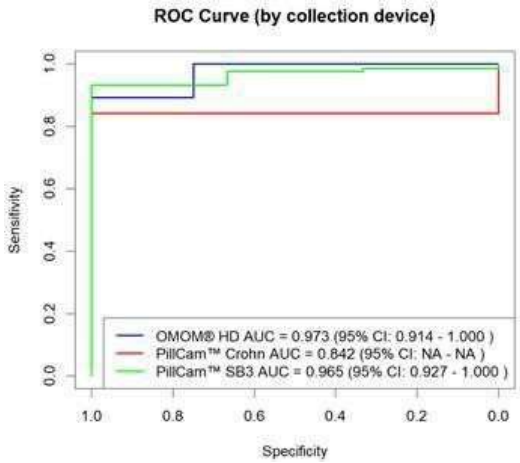
(1) Collection site: Centro Hospitalar Universitário São João; (2) Collection site: ManopH - Laboratório de Endoscopia e Motilidade Digestiva, Lda.

Subgroup analyses for patient-level sensitivity and specificity did not identify major differences when analyzed by gender, age, collection device, collection site and clinical indication.









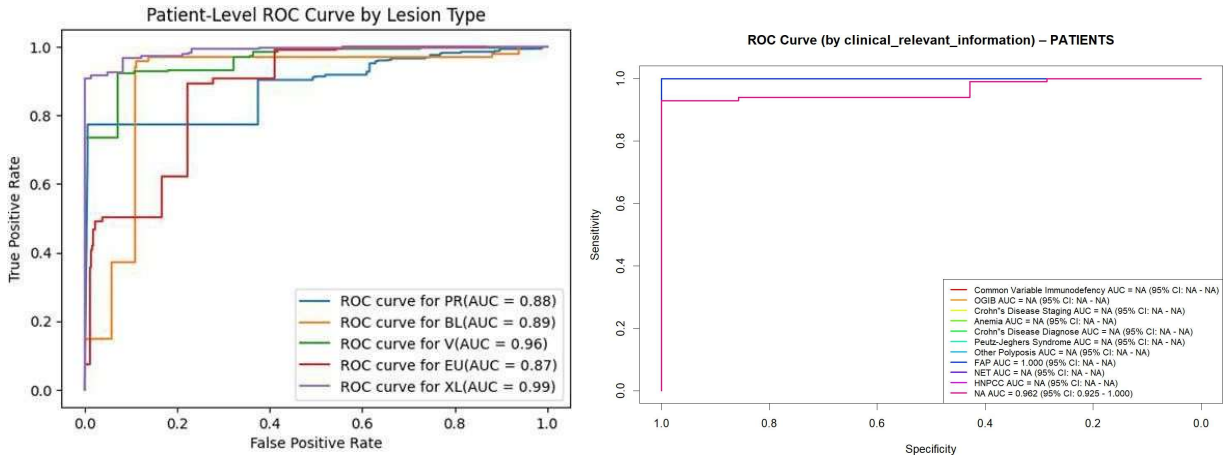


Figure 3: Patient-Level Subgroups ROC and AUC Analysis.

b. <u>Image-Level Analysis</u>

Table 7: Image-level Analysis Results.

	Expert Reading		**Sensitivity (95% CI)**	**Specificity (95% CI)**	**AUC**
Deep Capsule Prediction	Lesion	Normal	**0.921** (0.919 - 0.923)	**0.880** (0.874 - 0.886)	**0.971** (0.970 - 0.972)
Lesion	76492	1565			
Normal	6549	11476			

Image level analysis refers to the analysis of the dataset consisting of normal (no lesion present) and abnormal (lesion present) images. This dataset may include multiple images of the same lesion from different angles. Image level sensitivity and specificity were determined to be 92.1% (95% CI: 91.9%-92.3%) and 88.0% (95% CI: 87.4%-88.6%), respectively. ROC and AUC analysis is shown below in Figure 4.

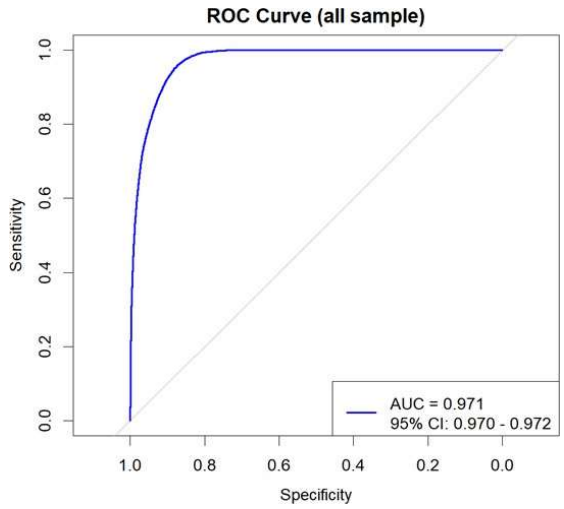


Figure 4: Image-Level ROC and AUC Analysis.

Results of subgroup analyses based on gender, age range, collection site, device and clinical indication are presented in Table 8 and Figure 5.

Table 8: Image-level Subgroups Analysis Results.

	Deep Capsule Prediction	Expert Reading		Sensitivity (95% CI)	Specificity (95% CI)	AUC
		Lesion	Normal			
PillCam™ SB3	Lesion	55761	225	**0.912** (0.909 - 0.914)	**0.977** (0.974 - 0.980)	**0.984** (0.983 - 0.985)
	Normal	5407	9677			
PillCam™ Crohn	Lesion	13460	1338	**0.945** (0.941 - 0.948)	**0.545** (0.527 - 0.563)	**0.934** (0.931 - 0.938)
	Normal	789	1604			
OMOM® HD	Lesion	7271	2	**0.954** (0.949 - 0.958)	**0.990** (0.964 - 0.999)	**0.996** (0.995 - 0.998)
	Normal	353	195			
Male	Lesion	38701	98	**0.935** (0.932 - 0.937)	**0.977** (0.971 - 0.981)	**0.990** (0.989 - 0.991)
	Normal	2701	4076			
Female	Lesion	37791	1467	**0.908** (0.905 - 0.910)	**0.835** (0.827 - 0.842)	**0.957** (0.956 - 0.959)
	Normal	3848	7400			
≤ 50 years old	Lesion	26397	60	**0.898** (0.894 - 0.901)	**0.986** (0.982 - 0.989)	**0.984** (0.983 - 0.985)
	Normal	3008	4279			
51-70 years old	Lesion	29756	163	**0.945** (0.942 - 0.947)	**0.953** (0.945 - 0.960)	**0.985** (0.984 - 0.986)
	Normal	1737	3280			
71+ years old	Lesion	20339	1342	**0.919** (0.915 - 0.922)	**0.745** (0.733 - 0.757)	**0.953** (0.951 - 0.955)
	Normal	1804	3917			
CHUSJ [(1)]	Lesion	69244	1563	**0.918**	**0.878**	**0.969**

	Deep Capsule Prediction	Expert Reading		Sensitivity (95% CI)	Specificity (95% CI)	AUC
		Lesion	Normal			
	Normal	6201	11281	(0.916 - 0.920)	(0.873 - 0.884)	(0.968 - 0.970)
ManopH (2)	Lesion	7248	2	**0.954** (0.949 - 0.959)	**0.990** (0.964 - 0.999)	**0.996** (0.995 - 0.998)
	Normal	348	195			
Common Variable Immunodefency	Lesion	12499	0	**0.971** (0.968 - 0.973)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	377	0			
NA	Lesion	27213	70	**0.936** (0.934 - 0.939)	**0.988** (0.984 - 0.990)	**0.990** (0.989 - 0.991
	Normal	1848	5572			
OGIB	Lesion	21898	27	**0.985** (0.984 - 0.987)	**0.887** (0.840 - 0.921)	**0.989** (0.982 - 0.996)
	Normal	325	211			
Crohn"s Disease Staging	Lesion	3327	1368	**0.985** (0.984 - 0.987)	**0.887** (0.840 - 0.921)	**0.989** (0.982 - 0.996)
	Normal	1434	2909			
Anemia	Lesion	8840	36	**0.839** (0.832 - 0.846)	**0.980** (0.972 - 0.985)	**0.970** (0.967 - 0.973)
	Normal	1697	1744			
Crohn"s Disease Diagnose	Lesion	2053	45	**0.779** (0.762 - 0.794)	**0.951** (0.935 - 0.963)	**0.916** (0.907 - 0.925)
	Normal	584	870			
Peutz-Jeghers Syndrome	Lesion	111	18	**0.782** (0.707 - 0.842)	**0.878** (0.815 - 0.921)	**0.902** (0.868 - 0.936)
	Normal	31	129			
Other Polyposis	Lesion	223	0	**0.729** (0.676 - 0.776)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	83	0			
FAP	Lesion	214	1	**0.699** (0.646 - 0.748)	**0.976** (0.877 - 0.996)	**0.940** (0.910 - 0.970)
	Normal	92	41			
NET	Lesion	59	0	**0.504** (0.415 - 0.593)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	58	0			
HNPCC	Lesion	55	0	**0.733** (0.624 - 0.820)	**NA** (NA - NA)	**NA** (NA - NA)
	Normal	20	0			

(1) Collection site: Centro Hospitalar Universitário São João; (2) Collection site: ManopH - Laboratório de Endoscopia e Motilidade Digestiva, Lda.

Subgroup analyses for image-level sensitivity and specificity did not identify major differences when analyzed by gender, age, collecting device, collecting site and clinical indication.

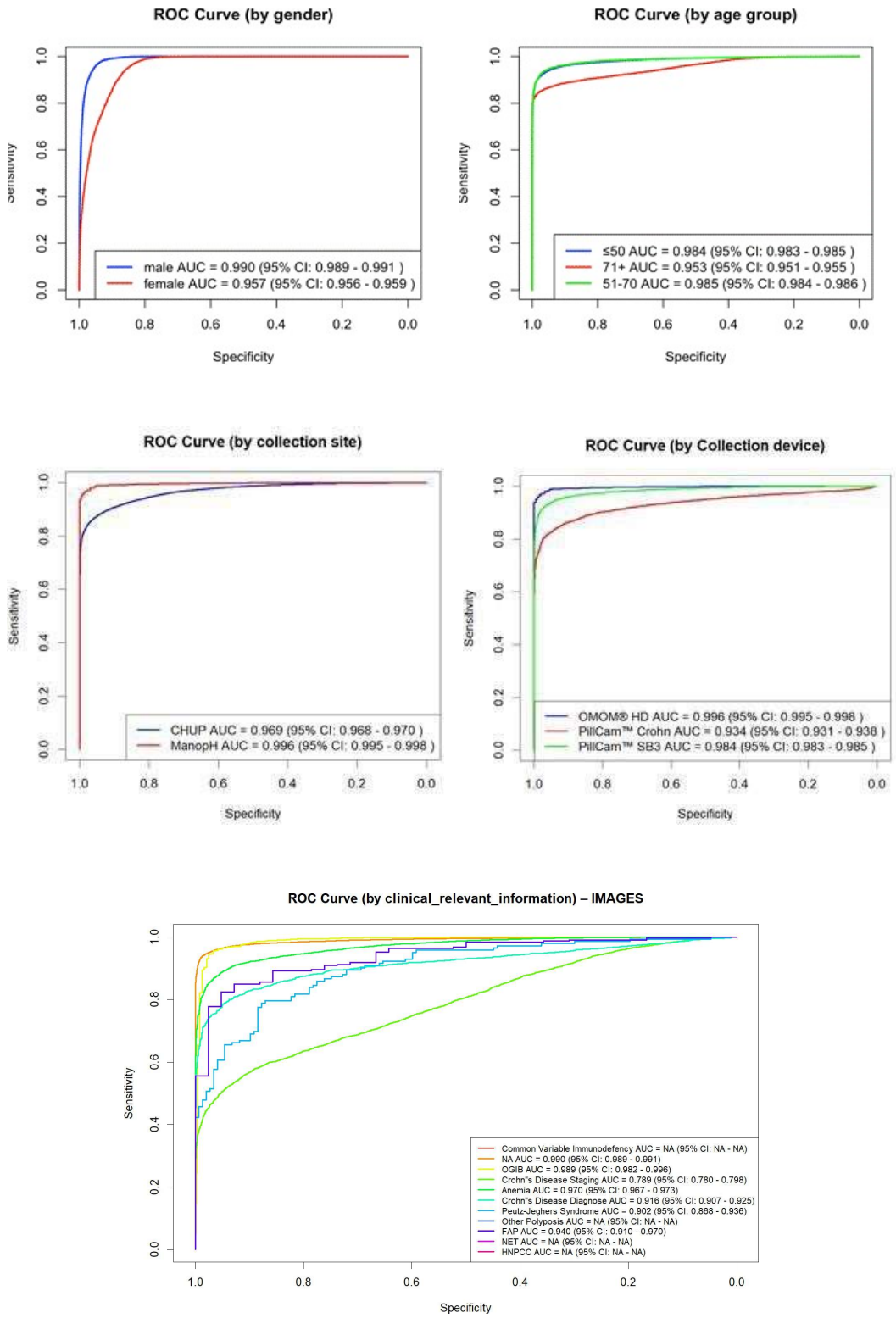


Figure 5: Image-Level Subgroups ROC and AUC Analysis.

Conclusions from Lesion Detection Testing

Patient-level sensitivity was high, at 95.8%, demonstrating that the lesion detection function resulted in few false negatives for patients. Patient level specificity was 75%, suggesting that clinicians will need to carefully review Deep Capsule® findings to identify false positive predictions. At the image-level, results demonstrate sensitivity of 92.1% and specificity of 88%.

Clinical Readers and Adjudication

The clinical validation study involved 15 board-certified gastroenterologists and 5 independent expert adjudicators. Participating clinicians were certified specialists in gastroenterology and/or digestive endoscopy with a minimum of 5 years of post-fellowship clinical experience. Readers were located across the United States, Portugal, Spain, and Brazil. There was no overlap between clinical readers and adjudicators.

Retrospective Clinical Validation Study

The clinical validation dataset included 330 capsule endoscopy examinations collected between January 2021 and April 2024 from seven independent clinical centers across four countries (Portugal, Spain, Brazil, and the United States). Table 9 presents the full clinical data set demographics.

Table 9: Demographics of clinical dataset.

Demographics Information (330 subjects)	
Mean Age, years (SD)	58.75 (18.14)
<=50 years, Number of Subjects (%)	112 (33.9%)
51 - 70 years, Number of Subjects (%)	109 (33.0%)
> 70 years, Number of Subjects (%)	109 (33.0%)
Sex, N (%)	
Female	179 (54.2%)
Male	151 (45.8%)
Country, Number of Subjects (%)	
USA	118 (35.8%)
Portugal	82 (24.8%)
Brazil	71 (21.5%)
Spain	59 (17.9%)
Collection Site, Number of Subjects (%)	
Hospital Nove de Julho (Brazil)	49 (14.8%)
Hospital Senhora da Oliveira (Portugal)	82 (24.8%)
Hospital Sirio-Libanes Brasilia (Brazil)	15 (4.5%)
Hospital Universitario de la Princesa (Spain)	38 (11.5%)
Hospital Universitario Puerta de Hierro Majadahonda (Spain)	21 (6.4%)
Hospital Vila Nova Star (Brazil)	7 (2.1%)
USA Health University Hospital of South Alabama (USA)	118 (35.8%)
Collection Device, Number of Subjects (%)	
PillCam™ SB3	307 (93.0%)
Olympus EC-10®	21 (6.4%)
PillCam™ SB2	2 (0.6%)

Indication	
Anaemia, n (%)	166 (50.6%)
Crohn's disease, n (%)	72 (22.0%)
Obscure gastrointestinal bleeding, n (%)	67 (20.4%)
Diarrhea, n (%)	11 (3.4%)
Genetic syndrome, n (%)	4 (1.2%)
GI tumor, n (%)	4 (1.2%)
Celiac disease, n (%)	2 (0.6%)
Abdominal pain, n (%)	1 (0.3%)
Weight loss, n (%)	1 (0.3%)
No information	*2*
Race/ethnicity	
White or Caucasian	252 (76.4%)
Black or African-american	38 (11.5%)
Hispanic or Latino	36 (10.9%)
Asian	2 (0.6%)
American Indian or Alaska Native	1 (0.3%)
Native Hawaiian or other pacific islander	1 (0.3%)

All clinical validation sites were independent from the institutions used for model development (Centro Hospitalar Universitário São João and ManopH, Portugal). No overlap existed between training and validation datasets.

Per-Patient Analysis

Diagnostic Yield

Table 10 summarises diagnostic yield (DY) for AI-assisted and Standard-of-Care (SoC) interpretation compared with the expert board reference standard. AI-assisted capsule endoscopy demonstrated non-inferiority to SoC ($p < 0.001$). Adjusted analyses accounting for prespecified covariates demonstrated consistent results.

Table 10. Diagnostic yield Per-patient level. Diagnostic yield of AI-assisted vs. standard-of-care capsule endoscopy, with comparison to expert board ground truth; raw and adjusted estimates with 95% CIs shown.

Statistical Information	AI-aided CapE	SoC	Expert board (Ground truth)
Unadjusted (raw estimates)			
n positive/ N total	317/330	251/330	290/330
Diagnostic Yield (DY)	0.961 (0.934 - 0.977)	0.761 (0.712 - 0.803)	0.879 (0.839 - 0.910)
Difference in DY between AI-aided and SoC	0.200 (0.149 - 0.251) Non-inferiority: established ($p < 0.001$)		
Adjusted			
Diagnostic Yield (DY)	0.968 (0.936 - 0.984)	0.777 (0.676 - 0.853)	

Difference in DY between AI-aided and SoC	0.191 (0.083 – 0.308) Non-inferiority: established (p < 0.001)	

Diagnostic Yield by Subgroups

Diagnostic yield was evaluated across prespecified demographic and clinical subgroups. Performance was consistent across all evaluated categories. Table 11 presents subgroup analyses including demographic (age, gender, race/ethnicity), clinical (indication), device type, and investigation site categories.

Table 11: Diagnostic yield by demographic subgroups.

		N	AI-aided CapE	SoC
Gender*	Female	179	0.965 (0.929 - 0.983)	0.762 (0.651 - 0.847)
	Male	151	0.970 (0.938 - 0.986)	0.790 (0.682 - 0.868)
Age Range*	<=50 years	112	0.967 (0.930 - 0.985)	0.771 (0.650 - 0.859)
	51 - 70 years	109	0.967 (0.930 - 0.985)	0.771 (0.651 - 0.858)
	> 71 years	109	0.970 (0.936 - 0.986)	0.788 (0.673 - 0.870)
Country**	USA	118	0.986 (0.970 - 0.994)	0.888 (0.823 - 0.931)
	Portugal	82	0.944 (0.894 - 0.971)	0.651 (0.543 - 0.745)
	Brazil	71	0.963 (0.925 - 0.982)	0.743 (0.637 - 0.827)
	Spain	59	0.973 (0.941 - 0.988)	0.802 (0.690 - 0.880)
Collection device**	PillCam™ SB3	307	0.973 (0.948 - 0.986)	0.800 (0.738 - 0.851)
	Olympus EC-10®	21	0.958 (0.891 - 0.984)	0.719 (0.518 - 0.859)
Clinical indication**	Anaemia	166	0.978 (0.955 - 0.990)	0.852 (0.783 - 0.902)
	Crohn's disease	72	0.957 (0.911 - 0.980)	0.741 (0.619 - 0.835)
	Obscure gastrointestinal bleeding	67	0.962 (0.920 - 0.982)	0.762 (0.649 - 0.847)
Race/ ethnicity**	White or Caucasian	252	0.968 (0.939 - 0.983)	0.772 (0.704 - 0.829)
	Black or African-american	38	0.992 (0.975 - 0.998)	0.935 (0.839 - 0.975)
	Hispanic or Latino	36	0.970 (0.929 - 0.988)	0.785 (0.644 - 0.881)
Collection Site	USA Health University Hospital	118	1.000 (0.968–1.000)	0.788 (0.706–0.852)
	Hospital Senhora da Oliveira	82	0.878 (0.790–0.932)	0.573 (0.465–0.675)
	Hospital 9 de Julho	49	0.980 (0.893–0.996)	0.959 (0.863–0.989)
	Hospital Sírio-Libanês	15	1.000 (0.796–1.000)	1.000 (0.796–1.000)
	Hospital Univ. La Princesa	38	1.000 (0.908–1.000)	0.737 (0.580–0.850)
	Hospital Univ. Puerta de Hierro	21	0.905 (0.711–0.973)	0.714 (0.500–0.862)
	Hospital Vila Nova Star	7	1.000 (0.646–1.000)	0.857 (0.487–0.974)

NOTE: analysis was not done for the device PillCam™ SB2 and for other levels of clinical indication and race/ethnicity due to very small sample sizes.
* based on a generalized linear mixed-effects models with gender and age group (fixed effects) and reader and patient (random effects); ** non-adjusted estimates obtained through logistic regression models.

Performance was consistent across evaluated subgroups. Certain categories with small sample sizes were not analyzed separately.

Per-Patient Diagnostic Performance Metrics

Sensitivity, specificity, PPV, and NPV were calculated relative to the expert board reference standard. Table 12 summarizes sensitivity, specificity, PPV, and NPV results.

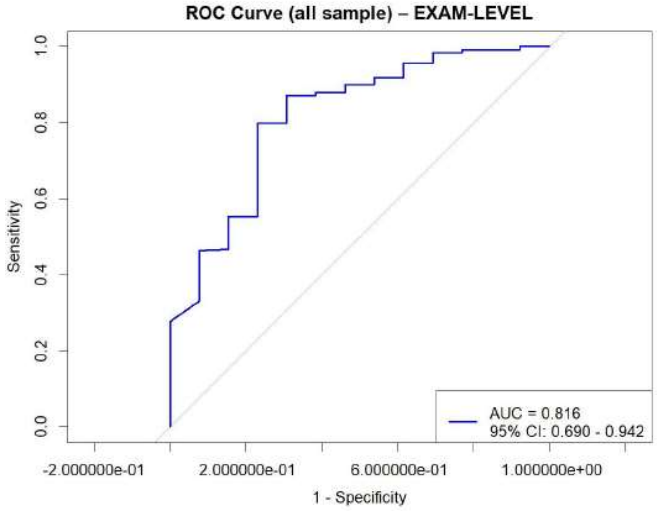
Table 12-1: Per-Patient Diagnostic Performance (Raw Estimates). Sensitivity, Specificity, Positive predictive value (PPV), and Negative predictive value (NPV) for AI-aided and SoC methods – raw estimates.

	AI-aided CapE	SoC	p
Sensitivity	0.972 (0.947 - 0.986)	0.762 (0.710 - 0.807)	< 0.001
Specificity	0.125 (0.055 - 0.261)	0.250 (0.142 - 0.402)	0.131
PPV	0.890 (0.850 - 0.920)	0.880 (0.835 - 0.915)	< 0.001
NPV	0.385 (0.177 - 0.645)	0.127 (0.070 - 0.218)	-

AI-assisted interpretation demonstrated substantially higher sensitivity compared to Standard-of-Care.

Table 12-2: Deep Capsule Model Patient-Level Classification Performance Compared to Expert Reading. Evaluation on Clinical Validation Set.

Deep Capsule Prediction	Expert Reading		Sensitivity (95% CI)	Sensitivity (95% CI)	AUC
	Lesion	Normal			
Lesion	317	13	1.000 (0.988 - 1.000)	0.000 (0.000 - 0.228)	0.816 (0.690 - 0.942)
Normal	0	0			
Total	317	13			



Deep Capsule Model Exam-Level ROC Curve. Evaluation on Clinical Validation Set.

Additional lesion-level analysis was conducted. The results highlight the model's prioritization of sensitivity while maintaining performance trends consistent with those observed in the internal test set.

Sensitivity and Specificity by Subgroup

Sensitivity and specificity were also evaluated across prespecified demographic, clinical, device, and site-level subgroups. AI-assisted interpretation consistently demonstrated higher sensitivity compared to Standard-of-Care. Specificity estimates varied across subgroups due to the high prevalence of positive cases in the clinical validation dataset, which limited precision of specificity estimates in certain sites. Site-level performance data are summarized below.

Table 13: Patient-Level Sensitivity and specificity by demographic subgroups.

	# negative/ positive/ total patients	Se/Sp (95% CI): unaided (SoC)	Se/Sp (95% CI): aided (AI)	Se/Sp (95% CI): aided - unaided difference
overall	40/290/330	Se: 76.2% (71 - 80.7) Sp: 25% (14.2 - 40.2)	Se: 97.2% (94.7 - 98.6), Sp: 12.5% (5.5 - 26.1)	Se: 21% (13.9 - 27.6) Sp: -12.5% (-34.7 - 11.9)
by gender				
Male	19/132/151	Se: 81.1% (73.5 - 86.8), Sp: 26.3% (11.8 - 48.8)	Se: 97% (92.5 - 98.8) Sp: 10.5% (2.9 - 31.4)	Se: 15.9% (5.6 - 25.3) Sp: -15.8% (-45.9 - 19.6)
Female	21/158/179	Se: 72.2% (64.7 - 78.6), Sp: 23.8% (10.6 - 45.1)	Se: 97.5% (93.7 - 99) Sp: 14.3% (5 - 34.6)	Se: 25.3% (15.1 - 34.3) Sp: -9.5% (-40.1 - 24)
by age range				
<=50 years	12/100/112	Se: 73% (63.6 - 80.7) Sp: 41.7% (19.3 - 68)	Se: 97% (91.5 - 99) Sp: 16.7% (4.7 - 44.8)	Se: 24% (10.8 - 35.4) Sp: -25% (-63.4 - 25.5)
51 - 70 years	12/97/109	Se: 75.3% (65.8 - 82.8) Sp: 25% (8.9 - 53.2)	Se: 96.9% (91.3 - 98.9) Sp: 8.3% (1.5 - 35.4)	Se: 21.6% (8.5 - 33.1) Sp: -16.7% (-51.7 - 26.5)
71+ years	16/93/109	Se: 80.6% (71.5 - 87.4), Sp: 12.5% (3.5 - 36)	Se: 97.8% (92.5 - 99.4), Sp: 12.5% (3.5 - 36)	Se: 17.2% (5.1 - 27.9) Sp: 0% (-32.5 - 32.5)
by country				
USA	0/118/118	Se: 78.8% (70.6 - 85.2), Sp: NA	Se: 100% (96.8 - 100) Sp: NA	Se: 21.2% (11.6 - 29.4) Sp: NA
Portugal	8/74/82	Se: 62.2% (50.8 - 72.4), Sp: 87.5% (52.9 - 97.8)	Se: 89.2% (80.1 - 94.4), Sp: 25% (7.1 - 59.1)	Se: 27% (7.7 - 43.6) Sp: -62.5% (-90.6 - 6.2)
Brazil	29/42/71	Se: 95.2% (84.2 - 98.7), Sp: 3.4% (0.6 - 17.2)	Se: 100% (91.6 - 100) Sp: 3.4% (0.6 - 17.2)	Se: 4.8% (-7.1 - 15.8) Sp: 0% (-16.6 - 16.6)
Spain	3/56/59	Se: 75% (62.3 - 84.5) Sp: 66.7% (20.8 - 93.9)	Se: 100% (93.6 - 100) Sp: 66.7% (20.8 - 93.9)	Se: 25% (9.1 - 37.7) Sp: 0% (-73.1 - 73.1)
by collection device				
PillCam™ SB3	27/270/307	Se: 75.9% (70.5 - 80.6), Sp: 21.6% (11.4 - 37.2)	Se: 97% (94.3 - 98.5) Sp: 8.1% (2.8 - 21.3)	Se: 21.1% (13.6 - 28) Sp: -13.5% (-34.4 - 9.9)
Olympus EC-10®	3/18/21	Se: 77.8% (54.8 - 91) Sp: 66.7% (20.8 - 93.9)	Se: 100% (82.4 - 100) Sp: 66.7% (20.8 - 93.9)	Se: 22.2% (-8.6 - 45.2), Sp: 0% (-73.1 - 73.1)

PillCam™ SB2	0/2/2	Se: 100% (34.2 - 100) Sp: NA	Se: 100% (34.2 - 100) Sp: NA	Se: 0% (-65.8 - 65.8) Sp: NA
by indication				
Abdominal pain	0/1/1	Se: 100% (20.7 - 100) Sp: NA	Se: 100% (20.7 - 100) Sp: NA	Se: 0% (-79.3 - 79.3) Sp: NA
Anaemia	13/153/166	Se: 80.4% (73.4 - 85.9), Sp: 30.8% (12.7 - 57.6)	Se: 97.4% (93.5 - 99) Sp: 15.4% (4.3 - 42.2)	Se: 17% (7.6 - 25.6) Sp: -15.4% (-53.3 - 29.6)
Celiac disease	0/2/2	Se: 100% (34.2 - 100) Sp: NA	Se: 100% (34.2 - 100) Sp: NA	Se: 0% (-65.8 - 65.8) Sp: NA
Crohn's disease	7/65/72	Se: 67.7% (55.6 - 77.8), Sp: 71.4% (35.9 - 91.8)	Se: 93.8% (85.2 - 97.6), Sp: 14.3% (2.6 - 51.3)	Se: 26.2% (7.4 - 42) Sp: -57.1% (-89.2 - 15.4)
Diarrhea	0/11/11	Se: 63.6% (35.4 - 84.8), Sp: NA	Se: 100% (74.1 - 100) Sp: NA	Se: 36.4% (-10.7 - 64.6) Sp: NA
Genetic syndrome	0/4/4	Se: 50% (15 - 85) Sp: NA	Se: 100% (51 - 100) Sp: NA	Se: 50% (-34 - 85) Sp: NA
GI tumour	0/4/4	Se: 75% (30.1 - 95.4) Sp: NA	Se: 100% (51 - 100) Sp: NA	Se: 25% (-44.4 - 69.9) Sp: NA
Obscure gastrointestinal bleeding	20/47/67	Se: 80.9% (67.5 - 89.6), Sp: 5% (0.9 - 23.6)	Se: 100% (92.4 - 100) Sp: 10% (2.8 - 30.1)	Se: 19.1% (2.9 - 32.5) Sp: 5% (-20.8 - 29.2)
Weight loss	0/1/1	Se: 0% (0 - 79.3) Sp: NA	Se: 100% (20.7 - 100) Sp: NA	Se: 100% (-58.7 - 100) Sp: NA
by race				
White or Caucasian	32/220/252	Se: 74.1% (67.9 - 79.4), Sp: 28.1% (15.6 - 45.4)	Se: 96.4% (93 - 98.1) Sp: 15.6% (6.9 - 31.8)	Se: 22.3% (13.6 - 30.2) Sp: -12.5% (-38.5 - 16.2)
Black or African-american	0/38/38	Se: 86.8% (72.7 - 94.2), Sp: N/A	Se: 100% (90.8 - 100) Sp: N/A	Se: 13.2% (-3.4 - 27.3) Sp: N/A
Hispanic or Latino	8/28/36	Se: 78.6% (60.5 - 89.8), Sp: 12.5% (2.2 - 47.1)	Se: 100% (87.9 - 100) Sp: 0% (0 - 32.4)	Se: 21.4% (-1.9 - 39.5) Sp: -12.5% (-47.1 - 30.2)
American Indian or Alaska Native	0/1/1	Se: 100% (20.7 - 100) Sp: N/A	Se: 100% (20.7 - 100) Sp: N/A	Se: 0% (-79.3 - 79.3) Sp: N/A
Asian	0/2/2	Se: 50% (9.5 - 90.5) Sp: N/A	Se: 100% (34.2 - 100) Sp: N/A	Se: 50% (-56.3 - 90.5) Sp: N/A
Native Hawaiian or other pacific islander	0/1/1	Se: 100% (20.7 - 100) Sp: N/A	Se: 100% (20.7 - 100) Sp: N/A	Se: 0% (-79.3 - 79.3) Sp: N/A
By collection site				

Hospital 9 de Julho (Brazil)	23 / 26 / 49	Se 96.2 (81.1–99.3) / Sp 4.3 (0.8–21.0)	Se 100.0 (87.1–100.0) / Sp 4.3 (0.8–21.0)	Se 3.8 (−12.2–18.9) / Sp 0.0 (−20.2–20.2)
Hospital Senhora da Oliveira (Portugal)	8 / 74 / 82	Se 62.2 (50.8–72.4) / Sp 87.5 (52.9–97.8)	Se 89.2 (80.1–94.4) / Sp 25.0 (7.1–59.1)	Se 27.0 (7.7–43.6) / Sp −62.5 (−90.6–6.2)
Hospital Sírio-Libanês Brasília (Brazil)	6 / 9 / 15	Se 100.0 (70.1–100.0) / Sp 0.0 (0.0–39.0)	Se 100.0 (70.1–100.0) / Sp 0.0 (0.0–39.0)	Se 0.0 (−29.9–29.9) / Sp 0.0 (−39.0–39.0)
Hospital Universitario La Princesa (Spain)	0 / 38 / 38	Se 73.7 (58.0–85.0) / Sp N/A	Se 100.0 (90.8–100.0) / Sp N/A	Se 26.3 (5.8–42.0) / Sp N/A
Hospital Universitario Puerta de Hierro (Spain)	3 / 18 / 21	Se 77.8 (54.8–91.0) / Sp 66.7 (20.8–93.9)	Se 100.0 (82.4–100.0) / Sp 66.7 (20.8–93.9)	Se 22.2 (−8.6–45.2) / Sp 0.0 (−73.1–73.1)
Hospital Vila Nova Star (Brazil)	0 / 7 / 7	Se 85.7 (48.7–97.4) / Sp N/A	Se 100.0 (64.6–100.0) / Sp N/A	Se 14.3 (−32.9–51.3) / Sp N/A
USA Health University Hospital of South Alabama (USA)	0 / 118 / 118	Se 78.8 (70.6–85.2) / Sp N/A	Se 100.0 (96.8–100.0) / Sp N/A	Se 21.2 (11.6–29.4) / Sp N/A

Notes: Subgroup results with small sample sizes should be interpreted with caution due to wider confidence intervals. Specificity could not be estimated in sites with no negative patients.

Across all prespecified demographic and clinical subgroups, AI-assisted interpretation demonstrated consistently higher sensitivity compared to Standard-of-Care. Specificity estimates varied across sites and subgroups due to low prevalence of negative cases in certain centers. No clinically meaningful degradation in performance was observed across age, gender, race/ethnicity, device type, or investigation site.

Image-level analysis

In addition to patient-level analysis, performance was evaluated at the image (frame) level. Each video frame was classified as Lesion-positive or Normal. Frame-level ground truth was established by expert reviewers blinded to AI outputs. Confusion matrices were generated comparing AI outputs and Standard-of-Care outputs against the expert reference standard.

Image-level analysis

The image-level (lesion-level) performance of Deep Capsule® was evaluated in a retrospective, multicenter clinical validation study, which included 330 capsule endoscopy examinations from seven independent clinical centers across four countries: the United States, Portugal, Brazil, and Spain.

Ground truth was established through independent manual review of full capsule endoscopy videos by two experienced gastroenterologists, with adjudication by an expert board in cases of disagreement. Reviewers establishing the reference standard were independent of the AI-assisted reading process.

Image-Level Confusion Matrix

Table 14 presents the overall image-level confusion matrix for AI-aided CapE versus the ground truth reference standard.

Table 14. Image-Level Confusion Matrix (AI-aided CapE vs Ground Truth)

Ground Truth	Lesion	Normal	Total
AI-aided CapE = Lesion	219,171	594,032	813,203
AI-aided CapE = Normal	14,044	3,348,145	3,362,189
Total	233,215	3,942,177	4,175,392

Overall Image-Level Performance and Subgroup Analyses

Overall image-level performance metrics (sensitivity, specificity, PPV, NPV, and AUC) are presented in Table 15, including subgroup analyses across gender, age range, country, capsule device, clinical indication, and race/ethnicity.

Table 15. Image-Level Performance (AI-aided CapE vs Ground Truth) – Overall and by Subgroup (Raw Estimates)

AI-aided CapE	Sensitivity (95% CI)	Specificity (95% CI)		PPV (95% CI)	NPV (95% CI)
Overall	94% (89.6 - 96.9)	84.9% (82.6 - 87.2)		27% (21.5 - 32.9)	99.6% (99.3 - 99.8)
by gender					
female	95.9% (92.3 - 98.3)	84.3% (80.7 - 87.3)		27.5% (18.6 - 36.8)	99.7% (99.5 - 99.9)
male	91.3% (82.7 - 96.9)	85.7% (82.2 - 88.5)		26.2% (21.1 - 31)	99.4% (98.9 - 99.8)
by age range					
0-50	97.6% (96.2 - 98.5)	86.3% (82.6 - 89.7)		28.2% (19.7 - 36.5)	99.8% (99.8 - 99.9)
51-70	98.4% (97.1 - 99.2)	73.4% (65.7 - 81.4)		21.6% (13.8 - 31.3)	99.8% (99.7 - 99.9)
71+	95.4% (90.5 - 98.6)	73.9% (65.5 - 82.1)		16.1% (9.7 - 24.2)	99.7% (99.2 - 99.9)
By country					
Brazil	96.4% (94.8 - 97.7)	89.9% (86.3 - 92.8)		38.7% (27.7 - 49.8)	99.7% (99.6 - 99.9)
Portugal	86.8% (70.9 - 96)	91.9% (89.5 - 93.9)		25.5% (15.5 - 36.3)	99.5% (99 - 99.9)
Spain	95.5% (89.1 - 98.9)	79.3% (73.3 - 84.9)		31.7% (18.7 - 44)	99.4% (98.9 - 99.9)
USA	97.5% (95.9 - 98.6)	74.3% (69.8 - 79.3)		19.6% (14.8 - 24.7)	99.8% (99.6 - 99.9)
By collection device					
PillCam™ SB3	94.5% (89.3 - 97.4)	85.1% (82.6 - 87.3)		27.5% (21.6 - 34.1)	99.6% (99.3 - 99.8)
PillCam™ SB2	59.7% (56.8 - 65.2)	97.8% (97.4 - 98.3)		7.2% (4.4 - 12)	99.9% (99.8 - 99.9)
Olympus EC-10®	87.2% (79.6 - 98.2)	82.5% (75.8 - 88.5)		21% (8.3 - 29.2)	99.2% (97.7 - 99.9)
By indication					
Crohn's disease	97.3% (94.9 - 98.6)	88.3% (83.9 - 91.6)		29.3% (17.5 - 41)	99.8% (99.7 - 99.9)
Anemia	92.8% (87.9 - 96.6)	82.6% (78.9 - 86)		20.9% (16.1 - 26.2)	99.6% (99.2 - 99.8)
Obscure GI bleeding	98.5% (95 - 99.4)	83.8% (75.8 - 89.8)		41% (22.9 - 57.9)	99.8% (99.7 - 99.9)
Abdominal pain	98.5% (98.5 - 98.5)	87.4% (87.4 - 87.4)		24.6% (24.6 - 24.6)	99.9% (99.9 - 99.9)
GI tumour	95.9% (95.5 - 98.9)	82.5% (67.4 - 97.4)		41.2% (9.7 - 49.2)	99.4% (98.3 - 100)
Diarrhea	57.7% (9.9 - 87.5)	89.9% (87 - 94.9)		20.1% (2.6 - 41.5)	98% (96.5 - 99.9)
Celiac disease	99.9% (98.6 - 100)	84.8% (76.2 - 96.3)		33.9% (33.8 - 34.4)	100% (100 - 100)
Weight loss	100% (100 - 100)	88.6% (88.6 -		0.9% (0.9 - 0.9)	100% (100 - 100)

		88.6)			
Genetic syndrome	99.8% (98.2 - 100)	87.1% (58.3 - 95.4)		30.1% (7.5 - 51)	100% (99.9 - 100)
By Race					
White or Caucasian	95% (91.3 - 97.3)	85.9% (83.5 - 88.1)		27.6% (20.9 - 35)	99.7% (99.5 - 99.8)
Black or African-american	97.5% (93.4 - 99.3)	70.2% (56.3 - 83.4)		28.9% (17.8 - 37.3)	99.6% (99 - 99.9)
Hispanic or Latino	80.4% (49.9 - 98.2)	85.8% (81.3 - 89.9)		20.4% (10.5 - 34.1)	99% (97.7 - 99.9)
American Indian or Alaska Native	100% (100 - 100)	59.4% (59.4 - 59.4)		3.1% (3.1 - 3.1)	100% (100 - 100)
Asian	99% (98.9 - 100)	86.2% (73.8 - 88.1)		15.6% (0.6 - 42.1)	100% (99.7 - 100)
Native Hawaiian or other pacific islander	99% (98.9 - 100)	86.2% (73.8 - 88.1)		15.6% (0.6 - 42.1)	100% (99.7 - 100)
By Collection Sites					
Hospital 9 de Julho (Brazil)	97.5% (96 - 98.6)	88.7% (84.1 - 92.6)		32.6% (21 - 43)	99.8% (99.7 - 99.9)
Hospital Senhora da Oliveira (Portugal)	86.8% (70.9 - 96)	91.9% (89.5 - 93.9)		25.5% (15.5 - 36.3)	99.5% (99 - 99.9)
Hospital Sírio-Libanês Brasília (Brazil)	90.7% (86.4 - 94.8)	92.9% (89.6 - 95.7)		34.1% (16.8 - 45.3)	99.6% (99.1 - 99.9)
Hospital Universitario La Princesa (Spain)	97.2% (91.3 - 99.4)	77.7% (68.5 - 85.2)		35% (18.9 - 51.4)	99.6% (99.1 - 99.9)
Hospital Universitario Puerta de Hierro (Spain)	87.2% (79.6 - 98.2)	82.5% (75.8 - 88.5)		21% (8.3 - 29.2)	99.2% (97.7 - 99.9)
Hospital Vila Nova Star (Brazil)	96.5% (95.1 - 98.2)	92.8% (87.2 - 97)		73.7% (35.6 - 90.8)	99.2% (98.4 - 99.9)
USA Health University Hospital of South Alabama (USA)	97.5% (95.9 - 98.6)	74.3% (69.8 - 79.3)		19.6% (14.8 - 24.7)	99.8% (99.6 - 99.9)

At the image level, AI-aided CapE demonstrated high sensitivity (94.0%; 95% CI: 89.6–96.9) and high specificity (84.9%; 95% CI: 82.6–87.2). Sensitivity remained high across evaluated demographic and technical subgroups, and specificity estimates were generally stable across strata. No systematic degradation in overall performance was observed across major demographic or technical subgroups.

Summary of Clinical Performance:

The clinical performance of Deep Capsule® was evaluated in a multicenter retrospective observational study designed to assess the performance of AI-assisted capsule endoscopy interpretation compared to conventional reading. The primary objective of the study was to assess the non-inferiority of AI-assisted reading for the detection of small bowel lesions using capsule endoscopy (CapE). Diagnostic yield (DY) was defined as the proportion of patients in whom at least one clinically relevant small bowel lesion was detected relative to the total number of patients examined.

Secondary objectives included the evaluation of diagnostic performance metrics (sensitivity, specificity, positive predictive value [PPV], and negative predictive value [NPV]) and comparison of mean reading time between AI-assisted and standard reading modalities.

A total of 330 capsule endoscopy examinations were included in the clinical validation dataset. Patients were enrolled from seven independent clinical centers located in Portugal, Spain, Brazil, and the United States. CapE exams were performed between January 2021 and April 2024 using three different capsule endoscopy systems: PillCam™ SB3, PillCam™ SB2, and Olympus EC-10®.

The study included 15 gastroenterologists experienced in capsule endoscopy, each with substantial prior reading experience. In the first phase of the study, videos were interpreted according to the standard of care (SoC) reading procedure by experts at the originating centers. In the second phase, anonymized videos were processed using the Deep Capsule® AI software, and AI-assisted readings were performed by independent expert readers blinded to the initial report and patient clinical data. In the AI-assisted arm, clinicians reviewed the AI-generated report and the capsule video and made the final determination regarding the presence of small bowel lesions.

An independent expert board composed of gastroenterologists with extensive capsule endoscopy experience served as the ground truth reference standard for the evaluation of diagnostic performance.

Comparison of Identification of Significant lesions vs Expert Board		**Expert Board Identification of lesions**		**Total**	**Diagnostic Yield (95% CI)**
		Yes	**No**		
Expert Board (Ground Truth)		290	40	NA	87.9% (83.9 - 91.2)
Standard Reading Mode (SoC)	**Yes**	221	10	231	76.1% (71.2–80.3)
	No	69	30	99	
AI + Physician Reading Mode (Deep Capsule®)	**Yes**	282	35	317	96.1% (93.4–97.8)

	No	8	5	13	

Conclusion: AI+Physician reading resulted in non-inferior diagnostic yield compared to standard of care reading and demonstrated high agreement with the expert board. Demonstrating that the use of Deep Capsule® does not negatively impact identification of patients with small bowel pathology. In addition, mean reading time was significantly reduced with AI+Physician reading, as compared to standard reading.

All clinical performance validation was completed premarket.

Usability Evaluation

A structured usability questionnaire completed by 33 gastroenterologists demonstrated high acceptance and positive feedback. User feedback showed high usability ratings (mean scores >4.5/5 in most areas) reinforcing its perceived value in routine practice.

Pediatric Extrapolation

In this 510(k) submission, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

Post-Market Surveillance

Deep Capsule® has completed clinical performance validation, standalone algorithm testing, and software verification and validation prior to submission. No elements of device performance validation are deferred to the postmarket phase.

Deep Capsule® will be monitored through routine postmarket activities consistent with regulatory requirements applicable to Class II devices.

Labeling

The labeling for Deep Capsule® includes a detailed description of the device and the patient population for which the device is indicated for use, and instructions for use. The Instructions for Use (IFU) provide information regarding system operation, workflow integration, and interpretation of AI-assisted outputs. The labeling also includes summary

information, including patient demographics, on the algorithm training, the non-clinical standalone performance testing and the clinical performance testing of the device in the clinical study (Study ID DC001).

The labeling includes limitations and warnings that prohibit the device from diagnosis or characterization of the lesions, and that the images and data acquired using the device are to be interpreted only by qualified medical professionals in reviewing small bowel capsule endoscopy videos. There is a warning that the device should not replace clinician decision-making. There is also a warning regarding overreliance on the device.

Conclusion:

Deep Capsule® is substantially equivalent to the legally marketed predicate device DEN230027 under 21 CFR 876.1540.

Based on the technological characteristics, intended use, and clinical performance data presented in this submission, Deep Capsule® does not raise different questions of safety and effectiveness compared to the predicate device.