



September 12, 2025

Odin Medical Limited
Luke Sampson
COO
74 Rivington Street
London, EC2A 3AY
United Kingdom

Re: K252586
Trade/Device Name: CADDIE
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP, SBX
Dated: August 15, 2025
Received: August 15, 2025

Dear Luke Sampson:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.

Assistant Director

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

OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252586

?

Please provide the device trade name(s).

?

CADDIE

Please provide your Indications for Use below.

?

The CADDIE computer-assisted detection device is intended to assist the gastroenterologist in detecting suspected colorectal polyps only. The gastroenterologist is responsible for reviewing CADDIE suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment.

CADDIE is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make a primary interpretation of endoscopic procedures, medical diagnosis, or recommendations of treatment/course of action for patients. The CADDIE computer-assisted detection device is limited for use with standard white-light endoscopy imaging only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) Summary

510(k) Number: K252586

510(k) Type: Special

Date Prepared: 15-Aug-2025

510(k) Owner: Odin Medical Ltd,
74 Rivington Street,
London EC2A 3AY
United Kingdom
Tel - +44 (0)7957 948411

Official Contact: Luke Sampson - COO

Submission Correspondent: Luke Sampson - COO

Proprietary or Trade Name: CADDIE

Common/ Usual Name: Gastrointestinal Lesion Software Detection System

Classification CFR: 21 CFR 876.1520

Classification Code: QNP, SBX

Classification Name: Gastrointestinal Lesion Software Detection System

Class: Class II

Predicate Device: K240044 CADDIE – Odin Medical LTD

Device Description:

CADDIE is cloud based artificial intelligence medical device software. CADDIE interfaces with the video feed generated by an endoscopic video processor during a colonoscopy procedure

The software is intended to be used by trained and qualified healthcare professionals as an accompaniment to video endoscopy for the purpose of drawing attention to regions with visual characteristics consistent with colonic mucosal lesions (such as polyps and adenomas).

CADDIE analyses the data from the endoscopic video processor in real-time and provides information to aid the endoscopist in detecting suspected colorectal polyps, if they are in the field of view of the endoscope.

The areas highlighted by CADDIE are not to be interpreted as definite polyps or adenomas. The responsibility to make a decision as to whether or not a highlighted region contains a polyp or is an adenoma lies with the user. The endoscopist is responsible for reviewing CADDIE suspected polyp areas and confirming the presence or absence of a polyp and its classification based on their own medical judgement.

Indications for Use:

The CADDIE computer-assisted detection device is intended to assist the gastroenterologist in detecting suspected colorectal polyps only. The gastroenterologist is responsible for reviewing CADDIE suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment.

CADDIE is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make a primary interpretation of endoscopic procedures, medical diagnosis, or recommendations of treatment/course of action for patients.

The CADDIE computer-assisted detection device is limited for use with standard white-light endoscopy imaging only.

Patient Population:

CADDIE is intended to be used on patients aged 45 and over referred for screening and surveillance endoscopic mucosal evaluations. This does not include pregnant women, for which no clinical evaluation has been carried out.

Environments of use:

Hospitals and clinics or in other secure endoscopy units where colonoscopies are performed.

Summary of Technological Characteristics:

At a high level we present the technological comparison of the subject device and the predicate in the **Table** below.

Summary of Technological Characteristics

Characteristics	Subject Device: CADDIE (Software version 1.5.0)	Predicate Device: CADDIE K240044 (Software version 1.4.13)	Comparison
Manufacturer	Odin Medical Ltd	Odin Medical Ltd	Same
Regulation Number	21 CFR 876.1520	21 CFR 876.1520	Same
Regulation Title	Gastrointestinal lesion software detection system	Gastrointestinal lesion software detection system	Same
Classification	Class II	Class II	Same
Classification Product Code	QNP, SBX	QNP, SBX	Same
Intended Use - definition	A gastrointestinal lesion software detection system is a computer-assisted detection device used in conjunction with endoscopy for the detection of abnormal lesions in the gastrointestinal tract. This device with advanced software algorithms brings attention to images to aid in the detection of lesions. The device may contain hardware to support interfacing with an endoscope.	A gastrointestinal lesion software detection system is a computer-assisted detection device used in conjunction with endoscopy for the detection of abnormal lesions in the gastrointestinal tract. This device with advanced software algorithms brings attention to images to aid in the detection of lesions. The device may contain hardware to support interfacing with an endoscope.	Same
Indications for Use	The CADDIE computer-assisted detection device is intended to assist the gastroenterologist in detecting suspected colorectal polyps only. The gastroenterologist is responsible for reviewing CADDIE suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment. CADDIE is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make a primary interpretation of endoscopic	The CADDIE computer-assisted detection device is intended to assist the gastroenterologist in detecting suspected colorectal polyps only. The gastroenterologist is responsible for reviewing CADDIE suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment. CADDIE is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make a primary interpretation of endoscopic	Same

Characteristics	Subject Device: CADDIE (Software version 1.5.0)	Predicate Device: CADDIE K240044 (Software version 1.4.13)	Comparison
	procedures, medical diagnosis, or recommendations of treatment/course of action for patients. The CADDIE computer-assisted detection device is limited for use with standard white-light endoscopy imaging only.	procedures, medical diagnosis, or recommendations of treatment/course of action for patients. The CADDIE computer-assisted detection device is limited for use with standard white-light endoscopy imaging only.	
Patient Population	CADDIE is intended to be used on patients aged 45 and over referred for screening and surveillance endoscopic mucosal evaluations. This does not include pregnant women, for which no clinical evaluation has been carried out.	CADDIE is intended to be used on patients aged 45 and over referred for screening and surveillance endoscopic mucosal evaluations. This does not include pregnant women, for which no clinical evaluation has been carried out.	Same
Technological Characteristics	CADDIE is standalone software that is deployed on the cloud and accessed via a web browser. The device is designed to highlight portions of the colon where the device detects potential colorectal polyps. CADDIE requires a network connection.	CADDIE is standalone software that is deployed on the cloud and accessed via a web browser. The device is designed to highlight portions of the colon where the device detects potential colorectal polyps. CADDIE requires a network connection.	Same
Convenience Features	When the clinician confirms the cecum and photo documents the cecal landmarks in standard clinical workflow, Cecum AI is triggered, and the image is sent for analysis. If the cecal landmarks are confirmed in the image, by the AI, the user will be given a reminder to check the status of Polyp detection. If polyp detection is turned off, the cross icon will flash three times along with the cecum icon. If detection is on, the cecum icon will flash three times next to the tick icon. This is a convenience feature that provides a check to the user that the CADDIE polyp detection function is on and in use.	When the clinician confirms the cecum and photo documents the cecal landmarks in standard clinical workflow, Cecum AI is triggered, and the image is sent for analysis. If the cecal landmarks are confirmed in the image, by the AI, the user will be given a reminder to check the status of Polyp detection. If polyp detection is turned off, the cross icon will flash three times along with the cecum icon. If detection is on, the cecum icon will flash three times next to the tick icon. This is a convenience feature that provides a check to the user that the CADDIE polyp detection function is on and in use.	Same, except the algorithm model of Cecum AI has been changed to another deep learning method, while the functionality of the feature remains unchanged. The performance has been evaluated through standalone performance testing. The results are satisfactory and do not raise any additional questions on the safety and effectiveness of the subject device.
Software	CADDIE utilizes an artificial intelligence-based	CADDIE utilizes an artificial intelligence-based	

Characteristics	Subject Device: CADDIE (Software version 1.5.0)	Predicate Device: CADDIE K240044 (Software version 1.4.13)	Comparison
Algorithm	algorithm to perform the polyp detection function.	algorithm to perform the polyp detection function.	
Device Output	During a colonoscopy, CADDIE generates markers, which look like green squares and are accompanied by a short, low-volume sound, and superimposes them on the video from the endoscope camera when it identifies a potential lesion.	During a colonoscopy, CADDIE generates markers, which look like green squares and are accompanied by a short, low-volume sound, and superimposes them on the video from the endoscope camera when it identifies a potential lesion.	Same

Discussion of Differences

The Indications for Use for both devices are identical; the subject device is an upgrade to the predicate device, without altering its Indications for Use.

Both the subject device and CADDIE (K240044) are identical in polyp detection.

Both devices take a colonoscopy video as an input from an endoscopy image processor and provide an output of a green bounding box that highlights the detected polyps.

Both devices are used in real-time to aid the clinician in detecting abnormal lesions live during a colonoscopy.

For cecal detection, there are changes in adopted algorithm models, however, both devices use artificial intelligence and deep learning algorithms in analyzing frozen images taken.

The subject and predicate device (CADDIE) share the same indications for use and principles of operation, and similar technological characteristics. There are minor technological differences that are addressed through performance testing, showing that these do not raise different questions of safety or effectiveness. The performance data demonstrates that the subject device is as safe and effective as the predicate device.

Performance Testing

This Special 510(k) addresses an update to the device's Convenience Feature (Cecum AI artificial intelligence (AI)) model algorithm. Performance testing was conducted to evaluate the updated model and is summarized below.

Other aspects of the device have not been modified in a manner that alters the safety or performance characteristics previously cleared under K240044. Changes to other aspects of the device that are not the subject of this submission have been evaluated through Odin's risk management process and FDA's guidance on deciding when to submit a 510(k) and determined not to require a new 510(k).

For all changes, design and development activities were performed in compliance with Odin's Quality Management System and FDA Design Control requirements (21 CFR 820.30), using the same methods and acceptance criteria described in the cleared submission (K240044). All performance characteristics continue to meet their established requirements and do not raise any additional questions associated with the safety and effectiveness of the device.

Special Control Technical Testing

Assessment of Pixel-level comparison of degradation of image quality due to the device, video delay due to marker annotation and the real-time endoscopic video delay due to the device have been carried out, using the same method and acceptance criteria described in the cleared submission (K240044). The result remains unchanged after the clearance of K240044.

Human Factors and Usability Testing

Human Factors and Usability Testing was conducted and reviewed in K240044 and is still applicable to the versions of the device that are the subject of this submission.

CADDIE Data Description and Non-Clinical testing

Cecum AI Convenience Feature Standalone Bench-testing Dataset

Standalone performance testing was performed to assess the ability of the Cecum AI Convenience Feature to discriminate between normal mucosa and cecal landmarks, such as the appendiceal orifice or the ileocecal valve, on photo-documented frames from a standard colonoscopy procedure. A set of recorded colonoscopy frames were analyzed by the Cecum AI Convenience Feature and the results were compared to the historical control (known cecal structure status per frame).

Annotation was performed on a per-frame basis, where a team of trained clinical annotators labelled cecal structures with a bounding box. These annotations were used as ground truth reference standards.

The table below shows the distribution of cecal structure characteristics.

	Positive Frames	Appendiceal Orifice (AO)	Ileocecal Valve (ICV)	Negative Frames	Total Frames
Static Dataset	838	461	418	4016	5733

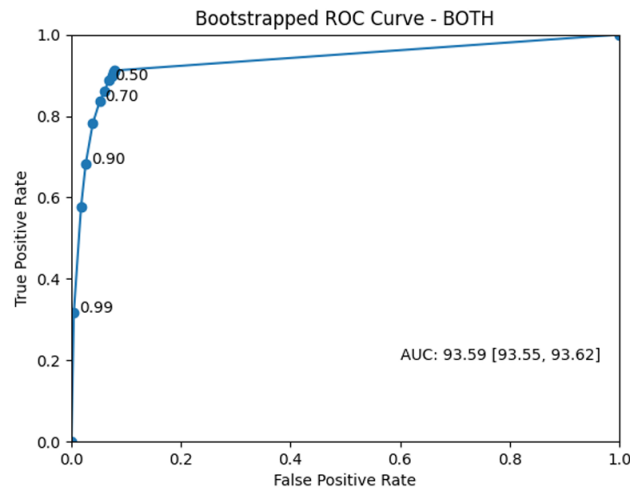
Cecum AI Convenience Feature Non-Clinical Performance Testing Results

Non-clinical performance testing was performed on the standalone bench-testing dataset, which is separate to the development datasets. The metrics in the following table correspond to the Cecum AI Convenience Feature endpoints and are grouped by type of data and cecal structure, when analyzed using a bootstrapping method with 1000 iterations, summarized as follows:

- Frame-level accuracy: proportion of frames correctly classified by the device
- Frame-level TPR: proportion of frames with cecum detected by the device
- Frame-level FPR: proportion of non-cecum frames where the device detects a cecal landmark

	Frame-level accuracy	Frame-level TPR	Frame-level FPR
Overall	90.38% [90.34, 90.43]	89.14% [89.06, 89.22]	9.18% [9.13, 9.24]
Structure			
Appendiceal Orifice (AO)	93.93% [93.90, 93.97]	83.39% [83.27, 83.51]	4.19% [4.16, 4.22]
Ileocecal Valve (ICV)	94.32% [94.29, 94.36]	83.78% [83.66, 83.91]	4.57% [4.54, 4.61]

The algorithm Receiver Operating Characteristic (ROC) curve and area Under the Curve (AUC) are shown in the figure below for the Cecum AI Convenience Feature considering Appendiceal Orifice and Ileocecal Valve as the positive class. The ROC curves illustrate the False Positive Rate versus the True Positive Rate at the frame level. The plot presents the non-parametric frame-level ROC curve, along with the estimated AUC and 95% confidence intervals, derived from patient-level bootstrapping.



Summary of Clinical Performance

The baseline Clinical Performance Evaluation was conducted and reviewed in K240044 and is still applicable to the versions of the device that are the subject of this submission.

Substantial Equivalence Conclusion

As the subject device is an updated version of the cleared CADDIE device, the two versions have identical indications for use and principles of operation, with similarity in technological characteristics. The technological difference of the subject of this 510(k) is addressed through performance testing, using methods, protocols, and acceptance criteria that supported the previously cleared 510(k), which shows that there are no new issues with safety or effectiveness. The performance data demonstrates that the subject device is substantially equivalent to the predicate device (K240044).