



December 11, 2025

Medcognetics, Inc.
John Jenkins
Chief Quality Officer
17217 Waterview Parkway
Suite 1.202E
Dallas, Texas 75252 USA

Re: K252482

Trade/Device Name: CogNet AI-MT+
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QFM
Dated: November 10, 2025
Received: November 10, 2025

Dear John Jenkins:

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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
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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.

K252482

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Please provide the device trade name(s).

?

CogNet AI-MT+

Please provide your Indications for Use below.

?

The MedCognetics CogNet AI-MT+ software is a passive notification for prioritization-only, parallel-workflow software tool used by MQSA qualified interpreting physicians to prioritize viewing patients with suspicious findings in the medical care environment. CogNet AI-MT+ utilizes an artificial intelligence algorithm to analyze DBT screening mammograms and flags those that are suggestive of the presence of at least one suspicious finding at the exam level.

CogNet AI-MT+ produces an exam level output to a PACS/Workstation for flagging the suspicious study and allows for worklist prioritization. MQSA qualified interpreting physicians are responsible for reviewing each exam on a display approved for use in mammography, according to the current standard of care. The CogNet AI-MT+ device is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the interpreting physician's worklist, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis.

The CogNet AI-MT+ device is intended for use with DBT mammography exams acquired using validated DBT equipment 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)

?

I. SUBMITTER

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Dallas, Texas 75252 USA

Phone: (214) 264-5612

Contact Person: John Jenkins

Date Prepared: June 10, 2025

II. DEVICE

Name of Device: CogNet AI-MT+

Common or Usual Name: CogNet AI-MT+

Classification Name: 21 CFR 892.2080 - Radiological computer aided triage and notification software

Regulatory Class: II

Product Code: QFM

III. PREDICATE DEVICE

CogNet QmTRIAGE (Renamed to CogNet AI-MT), K220080

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The MedCognetics CogNet AI-MT+ is a non-invasive computer-assisted triage and notification software as a medical device (SaMD) that analyzes DBT screening mammograms using a machine learning algorithm and notifies a PACS/workstation of the presence of findings suspicious of cancer in a study. The passive-notification enables interpreting physicians to prioritize their worklist and assists them in viewing prioritized studies using the standard PACS or workstation viewing software. The device aim is to aid in the prioritization and triage of radiological medical images only. It is a software tool for MQSA interpreting physicians reading mammograms and does not replace complete evaluation according to the standard of care.

The software modules that compose the CogNet AI-MT+ Deep Learning software are:

The Qualification Module - The requirement for acceptance into the CogNet AI-MT+ analysis is a completed Mammogram DICOM image. In the Qualification Module, the image arrives from the Mammogram modality and is “read” to

determine if this qualification applies.

The Mammogram Pre-Processing module – The DBT pixel brightness, image size, and shape is adjusted for consistency in this module. After the DICOM image has been qualified, the Pre-Processing module assures that the images are from a mammogram device and then validates that the DICOM is properly formed and consists of “For Presentation” image pixel data.

Mammogram Learning Module – This module accepts the normalized image data from the pre-processing module and uses Deep Learning techniques to extract features to determine if any lesions suspicious for cancer exist in the mammogram study

Failures in any of the above modules will generate error messages that are recorded in an accessible log file and, if user specific issues are encountered, sent to the user in a secondary capture report.

CogNet AI-MT+ has no viewing capability, but the results data are sent via a secure network function to the PACS/workstation, and the PACS/workstation “reads” the necessary DICOM tags and matches it with the original mammogram study images as a normal function of a PACS or Workstation.

When the study data is fed into the configured reading worklist, the results are merged as part of the mammogram study. This process allows an AI Result to be ready for prioritization of the study prior to the interpreting physician’s review.

A reading worklist is a listing of available studies for reading and diagnosis. The worklist is populated by the parsing of a DICOM file of a completed mammogram study, using the demographic and study fields to fill in the designated columns of the worklist. The columns are sortable by study, based on the column headings. CogNet AI-MT+ provides an API for adding an AI Results column with 0 to 1 response per study. If an analysis was not performed on that study, the AI Results indication is 0. If an analysis was performed on that study, then the AI Results column indicates either Suspicious (red diamond icon) or Processed (blue circle icon). The AI Results column may be sorted by the interpreting physicians by clicking an up or down arrow next to the column heading. This sort would allow the studies that contain suspicious findings to be brought to the top of the viewing list.

Device Inputs

Inputs to the CogNet AI-MT+ analysis software are digital copies of completed mammogram studies in DICOM format. Current or pre-existing DBT studies are uploaded as DICOM data into CogNet AI-MT+ via a DICOM network transfer from the facility's mammography imaging system, the facilities PACS, or DICOM router, depending on network configuration.

The criteria for the CogNet AI-MT+ software excludes patients with breast implants and post-surgical studies. Only tomographic studies are included in this submission as CogNet AI-MT+ is designed for analyzing DBT mammogram studies.

The imaging equipment manufacturer's model that has been validated with CogNet AI-MT+ is Hologic's Selenia Dimensions. The Hologic equipment was validated in tests executed in the CogNet AI-MT+ Design Validation (VAL-COG-060) and results discussed in the Validation Report.

Device Outputs

The outputs of CogNet AI-MT+ software is a DICOM secondary capture image that is not intended for diagnostic image review, and textual data of Suspicious or Processed results, as well as company information in DICOM private tags. These are the data that notifies the reading interpreting physicians of suspicious results.

Software Installation and Data Workflow

The CogNet AI-MT+ software is cloud based so installation is not required. The use of the product is by license only so the login for the user and User Instruction manual will be sent directly to the licensed individuals that will be accessing or responsible for the CogNet AI-MT+ device. MedCognetics quality and technical staff will coordinate and facilitate the initial usage.

Cybersecurity

MedCognetics is attentive to cybersecurity issues in medical devices. CogNet AI-MT+ is HIPAA compliant and assures that Personal Health Information is protected by promoting anonymization of data prior to analysis. This is accomplished by requiring de-identification as part of the data transfer to the CogNet AI-MT+ algorithm. DICOM data retains the necessary DICOM tags using these to merge the secondary capture image containing the CogNet analysis results into the original mammogram study for final viewing by a MQSA interpreting physician. DICOM data in network and in transfer to the CogNet AI-MT+ algorithm is encrypted in transit and at rest. User access is strictly password protected. The transferred data is subject to existing firewall solutions, auditing, and all interactions are logged to facilitate review of potential issues.

User Instruction

A User instruction manual is provided for the software. The proposed labeling for the proposed device is included in the submission.

Standards Applied

The standards applied for the development of the system are listed below in Table 1.

Table 1: Standards Applied

Standard	Title of Standard
IEC 62304	Software Development Life Cycle
21 CFR Part 820	FDA Regulatory Requirements and Design Controls
DICOM PS3.1	Digital Image and Communications in Medicine

V. INDICATIONS FOR USE

The MedCognetics CogNet AI-MT+ software is a passive notification for prioritization- only, parallel-workflow software tool used by MQSA qualified interpreting physicians to prioritize patients with suspicious findings in a medical care environment. CogNet AI- MT+ utilizes an artificial intelligence algorithm to analyze DBT screening mammograms and flags those that are suggestive of the presence of at least one suspicious finding at the exam level. CogNet AI-MT+ produces an exam level output to a PACS/Workstation for flagging the suspicious study and allows for worklist prioritization.

MQSA qualified interpreting physicians are responsible for reviewing each exam on a display approved for use in mammography, according to the current standard of care. The CogNet AI-MT+ device is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the interpreting physician's worklist, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis.

The CogNet AI-MT+ device is intended for use with DBT mammography exams acquired using validated equipment systems, only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The predicate device is CogNet AI-MT (formerly QmTRIAGE) for analysis of 2D FFDM mammography studies. CogNet AI-MT+, the proposed device, is designed to process only Digital Breast Tomosynthesis (DBT) Mammography images. These studies contain multiple "slices" of images so they must be evaluated individually, taking more time but offering a potentially better view of any lesions present in the breast. The difference between these two image modalities is in the separation and handling of the multi-frame images, but beyond that, the AI processing is virtually the same. On the next two pages is a list of technological characteristics and comparison between the predicate and the proposed device:

	New Device	Predicate Device (1)	Status
Trade Name	CogNet AI-MT+	CogNet QmTRIAGE	
510(k) Submitter [Number]	MedCognetics [K252482]	MedCognetics [K220080]	
Indication for Use	The MedCognetics CogNet AI-MT+ software is a passive notification for prioritization- only, parallel-workflow software tool used by MQSA qualified interpreting physicians to prioritize patients with suspicious findings in a medical care environment. CogNet AI- MT+ utilizes an artificial intelligence algorithm to analyze DBT screening mammograms and flags those that are suggestive of the presence of at least one suspicious finding at the exam level. CogNet AI-MT+ produces an exam level output to a PACS/Workstation for flagging the suspicious study and allows for worklist prioritization. MQSA qualified interpreting physicians are responsible for reviewing each exam on a display approved for use in mammography, according to the current standard of care. The CogNet AI-MT+ device is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the interpreting physician's worklist, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis. The CogNet AI-MT+ device is intended for use with DBT mammography exams acquired using validated equipment systems, only.	The MedCognetics (CogNet) QmTRIAGE software is a passive notification for prioritization-only, parallel-workflow software tool used by MQSA qualified interpreting physicians to prioritize patients with suspicious findings in the medical care environment. QmTRIAGE utilizes an artificial intelligence algorithm to analyze 2D FFDM screening mammograms and flags those that are suggestive of the presence of at least one suspicious finding at the exam level. QmTRIAGE produces an exam level output to a PACS/Workstation for flagging suspicious study and allows for worklist prioritization. MQSA qualified interpreting physicians are responsible for reviewing each exam on a display approved for use in mammography, according to the current standard of care. The QmTRIAGE device is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the interpreting physician's worklist, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis. The QmTRIAGE device is intended for use with 2D FFDM mammography exams acquired using validated FFDM systems, only.	Similar
Product Code(s)	QFM	QFM	Same
Regulation(s)	892.2080	892.2080	Same
Notification Only	Yes	Yes	Same
Parallel Workflow	Yes	Yes	Same
User	MQSA Interpreting physician	MQSA Interpreting physician	Same
Alert to finding	Yes. Passive notification flagged for review	Yes. Passive notification flagged for review	Same
Independent of SoC workflow	Yes. No cases are removed from	Yes. No cases are removed from worklist	Same

510(K) Summary: **K252482**

	New Device	Predicate Device (1)	Status
Trade Name	CogNet AI-MT+	CogNet QmTRIAGE	
510(k) Submitter [Number]	MedCognetics [K252482]	MedCognetics [K220080]	
	worklist		
Modality	DBT screening mammograms	FFDM screening mammograms	Different
Equipment Manufacturer	Hologic	Hologic	Same
Body Part	Breast	Breast	Same
AI algorithm	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same
Inclusion Criteria	• Standard DBT screening mammograms • Biopsy proven cancer studies (soft tissues and microcalcifications) • BIRADS 1 and 2 normal/benign cases with 2- year follow-up of a negative diagnosis • Female patients 22 and older • Bilateral Studies with 4 standard views (LCC, LMLO, RCC, RMLO)	• Standard 2D FFDM screening mammograms • Biopsy proven cancer studies (soft tissues and microcalcifications) • BIRADS 1 and 2 normal/benign cases with 2-year follow-up of a negative diagnosis • Female patients 22 and older • Bilateral Studies with 4 standard views (LCC, LMLO, RCC, RMLO)	Different
Aids in prompt identification of cases with indicated findings	Yes	Yes	Same
Results Preview	Secondary Capture stored with original DICOM study and may be viewed with the study. The device operates in parallel with the standard of care, which remains the default option.	Encapsulated PDF stored with original DICOM study and may be downloaded and viewed as a PDF. The device operates in parallel with the standard of care, which remains the default option.	Different
Deployment	Cloud based	Cloud based	Same
Where results are received	PACS / Workstation	PACS / Workstation	Same
Patient Contact	No direct or indirect contact	No direct or indirect contact	Same

	New Device	Predicate Device (1)	Status
Trade Name	CogNet AI-MT+	CogNet QmTRIAGE	
510(k) Submitter [Number]	MedCognetics [K252482]	MedCognetics [K220080]	
Cleaning	Not applicable	Not applicable	Same
Sterilization	Not applicable	Not applicable	Same

VII. PERFORMANCE DATA

The algorithm developed by MedCognetics is trained with samples both suspicious of cancer and not suspicious of cancer to build a model for predicting mammograms as "Suspicious" or Processed. During training, a batch of training examples are passed through the MLN which produces a batch of predictions (forward pass). The difference between the predictions and the ground truth labels is then measured using a loss function. Reverse-mode automatic differentiation is applied to determine how each model parameter should be updated to reduce the loss (backward pass). The parameter gradients produced during this process are then used by the optimizer to update the model parameters. This process is repeated for a fixed number of iterations, over which time the model's AUROC on both the training and development datasets are monitored to ensure that the model is not overfitting. Mammographic modalities utilized during training include FFDM, SFM, synthetic view, and DBT. Although the trained model will only process the DBT modality, we find that a diverse training set of modalities is beneficial to improving generalization.

Region	Total Patients	Positives	Negatives
Europe	2,372	40	2,332
South Asia	126	125	1
South America	4,066	577	3,489
South Asia	1,024	374	650
Europe	23,036	8,651	14,385
Africa	102	6	96
United States	1,566	723	843
Totals	32,292 (≈ 129,168 images)	10,496 (≈ 41,984 images)	21,796 (≈ 87,184 images)

Training Data Sources

A standalone retrospective study of device performance was conducted for the proposed device. The primary objective of the study was to assess the performance of the MedCognetics CogNet AI-MT+ algorithm for triage of DBT digital mammograms and validate the Area Under Receiver Operating Characteristics (AUROC) as ≥ 0.95 with a confidence interval of ± 0.02 at a confidence level of 95%. The secondary objective is to assess the sensitivity and specificity performance of the algorithm that will be comparable to the standard of care as reported in the Breast Cancer Surveillance Consortium (BCSC) study, which is 0.869 sensitivity and 0.889 specificity. The same parameters were used in the previous study for the predicate device.

Source	Data Pool (Patients)
Development Source 1	1292
Development Source 2	498

To ensure generalizability for all data sources, mammography images used for testing were obtained from a site or facility that was not used to source the training or development data. The training, development, and test set data sources were all separate and independent of each other. The study consisted of 806 women of screening age, grouped according to BI-RADS distribution. The study consisted of 403 cases with an assigned label of “benign” based on a negative diagnosis (BI-RADS 1 or 2 assessment) throughout 2-years of follow-up and 403 studies with a label of “malignant” based on a positive biopsy result. The predicate device’s study had similar inclusions and exclusions as the proposed device.

Biopsy Outcome	Biopsy Proven Benign	Malignant	Screening Benign
Samples	21	403	382
Positive	0	403	0
Negative	21	0	382

The performance of the CogNet AI-MT+ algorithm was analyzed across various subgroups of the test dataset. All stratified analysis was conducted using only Hologic Selenia Dimensions machines. The data was sorted into subgroups, including cohorts of Age; BIRADS; Breast Density; Lesion type; Pathology, Benign biopsy outcome, and Lesion size. The performance by subgroup was good but typically, dense breasts and small lesions are the most difficult to analyze and that is reflected in AUC being slightly less than 95%. Other than that, the subgroups all fell in the target range AUC of 95%. Similar results in the same subgroup breakdown from the predicate device.

Overall, CogNet AI-MT+ achieved an AUROC = 0.9548 (95% CI: 0.9364 - 0.9699) Sensitivity = 0.8809 (95% CI: 0.8511 - 0.9032) and Specificity = 0.9156 (95% CI: 0.8933 - 0.9380) was achieved, meeting the stated criteria. This compares

favorably with the predicate device performance of (AUROC) of 0.9569 with 95% CI: 0.9364-0.9738.

The proposed device and the predicate device's performance met or exceeded the primary objective of ≥ 95 AUC and the secondary objective of Sensitivity ≥ 0.89 and Specificity $\geq .889$.

VIII. CONCLUSION

The regulatory, usage, and process similarities are extensive between the proposed device and the predicate device, and the technical characteristics of the two devices are similar, as discussed in this submission. Any differences have been addressed and demonstrated to have no impact on the equivalence, safety, or effectiveness. In conclusion, as demonstrated through the supporting evidence contained within this submission, CogNet AI-MT+ is substantially equivalent to the identified predicate device and does not raise new or different questions of safety or effectiveness.