September 29, 2022

MedCognetics, Inc.
% Diane Rutherford
Regulatory Affairs Manager
17217 Waterview Parkway
Suite 1.202E
DALLAS TX 75252

Re: K220080
Trade/Device Name: CogNet QmTRIAGE
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: August 30, 2022
Received: August 30, 2022

Dear Diane Rutherford:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Kang, Ph. D.
Acting Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220080

Device Name
CogNet QmTRIAGE™

Indications for Use *(Describe)*
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 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 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 complete 2D FFDM mammography exams acquired using validated FFDM systems only.

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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5. 510(k) SUMMARY

a)

Submitter:	MedCognetics, Inc. Mr. Debasish "Ron" Nag Chief Executive Officer & President 17217 Waterview Parkway, Suite 1.202E Dallas, TX 75252 USA ron@medcognetics.com
Contact Person:	MedCognetics, Inc. Ms. Diane Rutherford Regulatory Affairs Manager 17217 Waterview Parkway, Suite 1.202E Dallas, TX 75252 USA TEL: 214-390-6569 diane@medcognetics.com
Date Prepared:	August 30, 2022 (*revised*)

b)

Trade Name:	CogNet QmTRIAGE
Common Name:	Radiological computer aided triage and notification software
Classification Name:	Radiological computer aided triage and notification software
Product Code:	QFM Class 2 Regulation Number 892.2080

c)

Predicate Devices:	K200905 Zebra Medical Vision Ltd. HealthMammo Cleared July 16, 2020

d)

Device Description:	The MedCognetics (CogNet) QmTRIAGE is a non-invasive computer-assisted triage and notification software as a medical device (SaMD) that analyzes 2D FFDM 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 radiologists 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. Data sets used for training the algorithm were independent of the testing datasets and were obtained from various sites worldwide including North America, South America, Europe, Africa, and Southeast Asia.

e)

Statement of Intended Use:	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 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 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 complete 2D FFDM mammography exams acquired using validated FFDM systems only.

f)

Summary of Technological Characteristics:

CogNet QmTRIAGE shares technological characteristics with the predicate device. Both are classified under the same product code and regulation, have the same intended use, flag suspicious images at the study/exam level, are parallel workflow processes that do not alter the original image, are non-contact, and are SaMD using AI for analysis.

The proposed device also has minor differences in technological characteristics from that of the predicate device. While both the proposed device and the predicate offer cloud-based analysis, the predicate also offers an on-premise option. The differences in the technological characteristics are minor and reflect market strategy and/or perceived user preferences and do not impact the safety, effectiveness, or substantial equivalence of the device.

Technological Characteristics	New Device [K220080] CogNet QmTRIAGE - MedCognetics	Predicate Device [K200905] HealthMammo - Zebra Medical Vision Ltd.	Status
Indication for Use / Intended Use	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 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 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 complete 2D FFDM mammography exams acquired using validated FFDM systems only.	The Zebra HealthMammo 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. HealthMammo 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. HealthMammo produces an exam level output to a PACS/Workstation for flagging the suspicious case and allows 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. HealthMammo 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 HealthMammo device is intended for use with complete 2D FFDM mammography exams acquired using validated FFDM systems only.	Same
Notification Only	Yes	Yes	Same
Parallel Workflow	Yes	Yes	Same
User	Interpreting physician	Interpreting physician	Same
Alert to finding	Yes. Passive notification flagged for review	Yes. Passive notification flagged for review	Same

Technological Characteristics		New Device [K220080] CogNet QmTRIAGE - MedCognetics	Predicate Device [K200905] HealthMammo - Zebra Medical Vision Ltd.	Status
Independent of SoC workflow		Yes. No cases are removed from worklist	Yes. No cases are removed from worklist	Same
Modality		FFDM screening mammograms	FFDM screening mammograms	Same
FFDM Manufacturer		Hologic	Hologic	Same
Body Part		Breast	Breast	Same
AI algorithm		Yes	Yes	Same
Limited to analysis of imaging data		Yes	Yes	Same
Performance Study	**Inclusion Criteria**	• Standard 2D FFDM screening mammograms • Biopsy proven cancer studies 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)	• 2D FFDM screening mammograms • Biopsy proven cancer studies (soft tissues and microcalcifications) • BIRADS 1 and 2 normal cases with 2 year follow-up • Studies with 4 standard views (LCC, LMLO, RCC, RMLO) BIRADS 1 and 2 normal cases with 2 year follow-up	*Different*
	Exclusion Criteria	• Digital breast tomosynthesis images • 2D synthetic views from tomosynthesis	• Digital Breast tomosynthesis studies • 3D studies • Studies that did not include all four views • Studies that do not comply with the inclusion criteria	*Different*
	Multiple Operating points	Not Applicable	Yes. Three optional operating points	*Different*
Aids in prompt identification of cases with indicated findings		Yes	Yes	Same
Results Preview		The device operates in parallel with the standard of care, which remains the default option for all cases. Encapsulated PDF stored with original DICOM study and may be downloaded and viewed as a PDF.	Presentation of notification and preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains the default option for all cases.	Equivalent
Deployment		Cloud based	Cloud based On-premise option	*Different*
Where results are received		PACS / Workstation	PACS / Workstation	Same

g)

Summary of Performance Testing:

The software was developed and validated in accordance with design controls and software documentation requirements for medical devices.

CogNet QmTRIAGE utilizes an artificial intelligence (AI) algorithm. The validation of the performance of MedCognetics' QmTRIAGE algorithm for triage of 2D FFDM achieved an overall Area Under Receiver Operating Characteristics (AUROC) of 0.9569 with 95% CI: 0.9364-0.9738 across the entire test dataset, without subgroup breakdown.

Also validated was Sensitivity and Specificity, achieving an overall Sensitivity of 87% and a Specificity of 89% across the entire test dataset, without subgroup breakdown, which exceeded the standard of care as reported in the Breast Cancer Surveillance Consortium (BCSC) study.

The performance of the MedCognetics' QmTRIAGE has been validated for triage of 2D FFDM in mammogram cases. The study data included a retrospective cohort of 800 anonymized 2D FFDM mammograms from the USA and Germany, including 399 cases positive for cancer with biopsy confirmation and 401 cases negative for breast cancer (BI-RADS1 and BI-RADS2) with a two-year follow-up of a negative diagnosis. The test dataset excludes screening BI-RADS 0 cases that were determined to be benign after diagnostic workup.

The mammogram cases were all from female patients, ages 22 to 80+ with the median age group being the 50-59 group. Ethnicities represented included American Indian, Asian, Black (non-Hispanic), Hispanic, and White (non-hispanic).

Imaging from Hologic, GE, Siemens, and Fujifilm, were used in the performance study and design validation but the complete vendor/model information was not provided with all images. The Hologic Selenia Dimension has been identified as the vendor/model for the initial release.

The performance test was constructed to ensure that confounding factors that are present in the population are addressed in the data such that it is consistent with the population of women undergoing breast cancer screening examination. The confounding factors that were considered include 1) lesion type, 2) breast density 3) age and 4) race. The triage accuracy was measured for these cohorts against the ground-truth.

Independence of test and training data was ensured by storing testing data in an isolated storage location. Once the relevant clinical sites had been identified for inclusion in the test set, all data from these sites were isolated into a controlled storage space. Data in this controlled storage space is only made available when conducting the performance test, ensuring total independence of the test set. Secondary software checks are also implemented against the list of cases in the training and test sets to further guarantee test set independence.

Conclusion:

MedCognetics considers CogNet QmTRIAGE to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use and performance testing of CogNet QmTRIAGE which demonstrated adequate performance for the device in line with its intended use.