May 23, 2024

VinBigData Joint Stock Company
℅ Nguyet (Jun) Phan
Regulatory Affairs Specialist
Symphony Office Building, Chu Huy Man Street, Vinhomes Riverside Ecological
Urban Area, Phuc Loi Ward, Long Bien District, Ha Noi
VIETNAM

Re: K233108
Trade/Device Name: VinDr-Mammo
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QFM
Dated: April 10, 2024
Received: April 23, 2024

Dear Nguyet (Jun) Phan:

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.

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 Imaging
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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.

Submission Number *(if known)*

K233108

Device Name

VinDr-Mammo

Indications for Use *(Describe)*

The VinDr-Mammo is a passive notification for prioritization-only, a parallel-workflow software tool used by MQSA qualified interpreting physicians to prioritize patients with suspicious findings in the medical care environment. VinDr-Mammo 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. VinDr-Mammo 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. VinDr-Mammo 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 VinDr-Mammo 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.

510(k) Summary

I. Submission Sponsor

VinBigData Joint Stock Company

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Contact: Phan (Jun) Minh Nguyệt

Title: Regulatory Affairs Specialist

Phone number: (+84) 326 066 2088

Date Prepared: 19 April 2024

Device Identification:

Trade/Proprietary Name:	VinDr-Mammo
Common/Usual Name:	Radiological computer aided triage and notification software
Classification Name:	Radiological computer aided triage and notification software
Regulation Number:	21 CFR 892.2080
Product Code:	QFM, Radiological Computer-Assisted Prioritization Software For Lesions
Device Class:	Class II
Classification Panel:	Radiology

II. Predicate Device

The VinDr-Mammo device is substantially equivalent to the following device:

Proprietary Name	CogNet QmTRIAGE
Premarket Notification	K220080
Classification Name	Radiological Computer-Assisted Prioritization Software
Regulation Number	21 CFR 892.2080
Product Code	QFM
Regulatory Class	II

III. Device Description

The *VinDr-Mammo* is an innovative medical device designed to assist in the analysis and triage of 2D full-field digital mammogram (FFDM) screening mammograms. Operating as non-invasive computer-assisted software, known as SaMD, it employs a machine learning algorithm to identify potential suspicious findings within the images. Once identified, the system promptly notifies a PACS/workstation for further examination. This passive-notification feature enables radiologists to prioritize their workload efficiently and view studies in order of importance using standard PACS or workstation viewing software. It is important to note that the VinDr-Mammo software is intended solely to aid in the prioritization and triage of radiological medical images. It serves as a valuable tool for MQSA interpreting physicians who specialize in mammogram readings, complementing the standard of care. It should be emphasized that the device does not replace the need for a comprehensive evaluation as per established medical practices. During the algorithm's training, independent datasets from various global sites were utilized, ensuring a robust and diverse training experience.

The *VinDr-Mammo code* can be viewed by radiologists on a Picture Archiving and Communication System (PACS), Electronic Patient Record (EPR), and/or Radiology

Information System (RIS) worklist and can be used to reorder the worklist: the mammographic studies with code 1 should be prioritized over those with code 0 and, thus, should be moved to the top of the worklist. As a software-only device, *VinDr-Mammo* can be hosted on a compatible host server connected to the necessary clinical IT systems such that DICOM studies can be received and the resulting outputs returned where they can be incorporated into the radiology worklist.

The following modules compose the *VinDr-Mammo* software:

- Data input and validation: Following retrieval of a study, the validation feature assessed the input data (i.e. age, modality, view) to ensure compatibility for processing by the algorithm.
- VinDr-Mammo algorithm: Once a study has been validated, the algorithm analyzes the 2D FFDM screening mammogram for detection of suspected findings.
- API Cognitive service: The study analysis and the results of a successful study analysis are provided through an API service, whose outputs will then be sent to the appropriate clinical IT system for viewing on a radiology worklist.
- Error codes feature: In the case of a study failure during data validation or the analysis by the algorithm, an error is provided to the system.

IV. Intended Use/Indication for Use

The *VinDr-Mammo* is a passive notification for prioritization-only, a parallel-workflow software tool used by MQSA qualified interpreting physicians to prioritize patients with suspicious findings in the medical care environment. *VinDr-Mammo* 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. *VinDr-Mammo* 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. *VinDr-Mammo* 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 *VinDr-Mammo* device is intended for use with complete 2D FFDM mammography exams acquired using validated FFDM systems only.

V. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the *VinDr-Mammo* device are substantially equivalent to the predicate device cited above.

A comparison of the technological characteristics with the predicate is summarized below.

Technological Characteristics	**Proposed Device VinDr-Mammo**	**Predicate Device CogNet QmTRIAGE (K220080)**	**Summary**
Indication for Use/Intended Use	The VinDr-Mammo 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. VinDr-Mammo utilizes an artificial intelligence	The MedCognetics (CogNet) QmTRIAGETM 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	Same

	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. VinDr-Mammo 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. VinDr-Mammo device is limited to the categorization of exams, does not provide any diagnostic	care environment. QmTRIAGETM 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. QmTRIAGETM 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	

	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 VinDr-Mammo device is intended for use with complete 2D FFDM mammography exams acquired using validated FFDM systems only.	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.	
Notification-only, parallel workflow tool	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
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 manufacturers have been validated	GE, Siemens, Fujifilm	Hologic	Same
Body part	Breast	Breast	Same
AI algorithm	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same
Inclusion Criteria	- Standard 2D FFDM screening mammograms - Biopsy proven cancer studies (soft tissues and microcalcifications) - Biopsy-proven benign studies	- Standard 2D FFDM screening mammograms - Biopsy proven cancer studies (soft tissues and microcalcifications) - BIRADS 1 and 2 normal/benign cases	Equivalent

	- BIRADS 1 and 2 normal cases with 2-year follow-up of a negative diagnosis - Bilateral Studies with 4 standard views (LCC, LMLO, RCC, RMLO)	with 2-year follow-up of a negative diagnosis - Female patients 22 and older - Bilateral Studies with 4 standard views (LCC, LMLO, RCC, RMLO)	
Exclusion Criteria	-Studies that do not include all 4 views -Digital Breast tomosynthesis studies - 3D studies Studies that do not comply with the inclusion criteria	- Digital breast tomosynthesis images - 2D synthetic views from tomosynthesis	Similar, different criteria and scope are intended to limit to specific mammography methods. This does not raise any questions regarding safety or efficacy and use of mammography images
Aids prompt identification of cases with indicated findings	Yes	Yes	Same

Multiple operating points	No Applicable	Not Applicable	Same
Preview Images	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.	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.	Equivalent
Where results are received	PACS / Workstation	PACS / Workstation	same

VI. Performance Data

Safety and performance of VinDr-Mammo has been evaluated and verified in accordance with software specifications and applicable performance standards through Software Development and Validation & Verification Process to ensure performance according to specifications, User Requirements and Federal Regulations and Guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The performance of the VinDr-Mammo device has been validated in two separate pivotal studies. The first study employed 2D digital mammograms (FFDM) provided by the Radiological Society of North America (RSNA) via their RSNA Screening

Mammography Breast Cancer Detection AI Challenge. The second was a performance study for triage of 2D FFDM screening mammogram cases from two Vietnamese hospitals.

The RSNA dataset was used to demonstrate the generalizability of the device to the demographics of the US population. The data set consisted of 1000 2D FFDM mammogram exams including 252 cases positive for cancer with histologically proven and 748 cases negative for breast cancer (BI-RADS 1, BI-RADS 2 and biopsy-proven benign) with a two-year follow-up of a negative diagnosis. A table of results is provided below:

Metrics	Mean	Lower 95% CI bound	Upper 95% CI bound
Sensitivity	0.889	0.849	0.926
Specificity	0.906	0.885	0.927
AUC	0.958	0.945	0.970

A summary of the DDSM dataset characteristics are provided in the table below:

Characteristics	Quantity/Type
Characteristics	Quantity/Type
Number of Studies	1000
Number of Images	5126
Number of Patients	1000
Density A	100
Density B	400
Density C	400
Density D	100
Age (<40)	14
Age (40-49)	266
Age (50-59)	266

Characteristics	Quantity/Type
Age (60-69)	251
Age (70-79)	155
Age (≥80)	46
Ethnicity	Representative of the US Population
Scanner Type	Unknown

Due to lack of scanner information from the RSNA dataset, a secondary dataset of 2D FFDM from a frontline Vietnamese hospital (Hanoi Medical University Hospital) was used to demonstrate the generalizability to different screening modalities. The data included a retrospective cohort of 1864 anonymized 2D FFDM mammograms, including 466 cases positive with biopsy-confirmed cancers and 1398 cases negative for breast cancer (BIRADS1, BIRADS2 and biopsy-proven benign) with a two-year follow-up of a negative diagnosis.

To ensure the data addressed confounding factors present in the population of women undergoing breast cancer screening, the test set was carefully constructed. Several factors, such as lesion type, breast density, age, and histology type, were considered. The accuracy of stand-alone detection and triage was measured on this cohort against the ground truth. A table of results is provided below:

Metrics	Mean	Lower 95% CI bound	Upper 95% CI bound
Sensitivity	0.906	0.879	0.931
Specificity	0.911	0.896	0.926
AUC	0.965	0.957	0.971

A summary of the Vietnamese data set characteristics are provided in the table below:

Characteristics	Quantity/Type
Number of Studies	1864
Number of Images	5126
Number of Patients	1864
Density A	180
Density B	746
Density C	746
Density D	192
Age (<40)	327
Age (40-49)	430
Age (50-59)	421
Age (60-69)	388
Age (70-79)	231
Age (≥80)	67
Ethnicity	Vietnamese
Hologic (Selenia Dimensions 3000)	517
Siemens (Mammomat Inspiration)	499
Fujifilm (AMULET Innovality)	482
GE (Senographe Essential ADS)	366

The aggregate results for both the RSNA and Vietnamese data sets are provided in the table below:

Metrics	Mean	Lower 95% CI bound	Upper 95% CI bound
Sensitivity	0.900	0.877	0.921
Specificity	0.910	0.897	0.922

AUC	0.962	0.957	0.971

This performance is substantially equivalent to that of the predicate (K220080). A table of the predicate results is provided below:

Metrics	**Mean**	**Lower 95% CI bound**	**Upper 95% CI bound**
Sensitivity	0.870	_	_
Specificity	0.890	_	_
AUC	0.957	0.936	0.973

To further assess VinDr-Mammo's performance, we analyzed results across four key factors: *breast density*, *age group*, *scanner model*, and *lesion type*. The following tables illustrate how the Area Under the Curve (AUC) metric remains consistent across these various subgroups.

Breast Density	**RSNA Test set**	**VinDr Test set**
A	0.964 (0.922-0.994)	1.000 (1.000-1.000)
B	0.967 (0.952-0.981)	0.990 (0.983-0.996)
C	0.946 (0.922-0.967)	0.908 (0.886-0.928)
D	0.949 (0.922-0.975)	0.947 (0.912-0.975)

Age group	**RSNA Test set**	**VinDr Test set**
Age (<40)	1.000 (1.000-1.000)	0.988 (0.975-0.997)
Age (40-49)	0.969 (0.947-0.985)	0.920 (0.894-0.943)

Age (50-59)	0.952 (0.915-0.983)	0.964 (0.948-0.978)
Age (60-69)	0.941 (0.921-0.960)	0.993 (0.986-0.997)
Age (70-79)	0.952 (0.916-0.982)	0.974 (0.933-0.997)
Age (≥80)	0.928 (0.873-0.977)	0.974 (0.939-0.997)
Scanner model	**RSNA Test set**	**VinDr Test set**
Hologic	-	0.968 (0.952-0.982)
Siemens	-	0.999 (0.997-1.000)
Fujifilm	-	0.969 (0.944-0.988)
GE	-	0.982 (0.961-0.996)

Lesion type	**RSNA Test set**	**VinDr Test set**
Mass	-	0.966 (0.951-0.979)
Calcification	-	0.963 (0.951-0.974)

A secondary endpoint was established to determine time performance of VinDr-Mammo to ensure that mammograms can be processed, and notification results returned for use by radiologists within minutes which is clinically acceptable. Lastly the timing performance for the device was shown to be an average of 2.8 minutes at a network speed of 10Mbits/s upload and 36Mbits/s download. This is well within the clinical operational expectations of the breast if biopsy-proven benign screening.

VII. Clinical Performance Data

There was no human clinical testing required to support the substantial equivalence of the subject device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

VIII. Conclusion

VinDr-Mammo has the same intended uses and similar indications, technological characteristics, and principles of operation as MedCognetics. The minor differences between the subject device and the predicate raise no new issues of safety or effectiveness. Performance data demonstrates that VinDr-Mammo performs as intended. Thus, VinDr-Mammo is substantially equivalent to the legally marketed predicate device.