VinBrain Joint Stock Company
℅ Nguyen Linh
Product Manager
No 7 Bang Lang 1 Street,
Vinhomes Riverside Ecological Urban Area
Viet Hung Ward, Long Bien District, Ha Noi
VIETNAM

September 1, 2022

Re: K221241
Trade/Device Name: DrAid for Radiology v1
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: July 22, 2022
Received: July 25, 2022

Dear Nguyen Linh:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: 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)*
K221241

Device Name
DrAid™ for Radiology v1

Indications for Use *(Describe)*
The DrAid™ for Radiology v1 is a radiological computer-assisted triage & notification software product designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of pneumothorax in medical care environment. DrAid™ analyzes cases using an artificial intelligence algorithm to features suggestive of suspected findings. It makes case-level output available to a PACS for worklist prioritization or triage.

As a passive notification for prioritization-only software tool with standard of care workflow, DrAid™ does not send a proactive alert directly to appropriately trained medical specialists. DrAid™ is not intended to direct attention to specific portions or anomalies of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out pneumothorax or otherwise preclude clinical assessment of X-Ray cases.

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
DrAid™ for Radiology v1

Name and Address of Applicant: VinBrain Joint Stock Company
No 7 Bang Lang 1 Street,
Vinhomes Riverside Ecological Urban Area,
Viet Hung Ward, Long Bien District,
Ha Noi, Vietnam

Date of Submission: April 29, 2022

Device Name: DrAid™ for Radiology v1

Product Code: QFM

Classification Name: Radiological computer aided triage and notification software

Regulation Number: 892.2080

Classification: Class II

Classification Panel: Radiology

Indications for Use:
The DrAid™ for Radiology v1 is a radiological computer-assisted triage & notification software product designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of pneumothorax in medical care environment. DrAid™ analyzes cases using an artificial intelligence algorithm to features suggestive of suspected findings. It makes case-level output available to a PACS for worklist prioritization or triage.

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Device Description:
DrAid™ for Radiology v1 (hereafter called DrAid™ or DrAid) is a a radiological computer-assisted triage & notification software product that automatically identifies suspected pneumothorax on frontal chest x-ray images and notifies PACS of the presence of pneumothorax in the scan. This notification enables prioritized review by the appropriately trained medical specialists who are qualified to interpret chest radiographs. The software does not alter the order or remove cases from the reading queue. The device's aim is to aid in the prioritization and triage of radiological medical images only.

Chest radiographs are automatically received from the user's image storage system (e.g. Picture Archiving and Communication System (PACS)) or other radiological imaging equipment (e.g. X-ray systems) and processed by DrAid™ for analysis. Following receipt of chest radiographs, the software device de-identifies a copy of each chest radiographs in DICOM format (.dcm) and automatically analyzes each image to identify features suggestive of pneumothorax. Based on the analysis result, the software notifies PACS/workstation for the presence of Pneumothorax as

indicating either “flag” or “(blank)”. This would allow the appropriately trained medical specialists to group suspicious exams together that may potentially benefit for their prioritization. Chest radiographs without an identified anomaly are placed in the worklist for routine review, which is the current standard of care.

The DrAid™ device works in parallel to and in conjunction with the standard care of workflow. After a chest x-ray has been performed, a copy of the study is automatically retrieved and processed by the DrAid™ device, therefore, the analysis result can also be provided in the form of DICOM files containing information on the presence of suspicious Pneumothorax. In parallel, the algorithms produce an on-device notification indicating which cases were prioritized by DrAid™ in PACS. The on-device notification does not provide any diagnostic information and it is not intended to inform any clinical decision, prioritization, or action to who are qualified to interpret chest radiographs. It is meant as a tool to assist in improving workload prioritization of critical cases. The final diagnosis is provided by the radiologist after reviewing the scan itself.

The following modules compose the DrAid™:

Data input and validation: Following retrieval of a study, the validation feature assessed the input data (e.g. age, modality, view) to ensure compatibility for processing by the algorithm.

AI algorithm: Once a study has been validated, the AI algorithm analyzes the frontal chest x-ray for detection of suspected pneumothorax.

API Cognitive service: The study analysis and the results of a successful study analysis are provided through an API service, to then be sent to the PACS for triaging & notification.

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.

Predicate Device:

DrAid™ for Radiology v1 is substantially equivalent to the HealthPNX (K190362) for Pneumothorax.

Substantial Equivalence Comparison:

A comparison of the subject and predicate device is provided in the table below.

	Subject	**Predicate**	**Comparison**
510(k) Number	Subject of submission	K190362	Subject Device Under Review
Device Name	DrAid™ for Radiology v1	HealthPNX	Subject Device Under Review
Manufacturer	VinBrain Joint Stock Company	Zebra Medical Vision Ltd.	Subject Device Under Review
Regulation Number	892.2080, Radiological computer aided triage and notification software	892.2080, Radiological computer aided triage and notification software	Identical

	Subject	Predicate	Comparison
Product Code	QFM, Radiological Computer-Assisted Prioritization Software For Lesions	QFM, Radiological Computer-Assisted Prioritization Software For Lesions	Identical
Target Anatomy	Chest/Lung	Chest/Lung	Identical
Image Modality	Frontal Chest X-ray	Frontal Chest X-ray	Identical
Targeted Clinical Condition	Pneumothorax	Pneumothorax	Identical
Indications for Use	The DrAid™ for Radiology v1 is a radiological computer-assisted triage & notification software product designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of pneumothorax in medical care environment. DrAid™ analyzes cases using an artificial intelligence algorithm to features suggestive of suspected findings. It makes case-level output available to a PACS for worklist prioritization or triage. As a passive notification for prioritization-only software tool with standard of care workflow, DrAid™ does not send a proactive alert directly to appropriately trained medical specialists. DrAid™ is not intended to direct attention to specific portions or anomalies of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule	The Zebra Pneumothorax device is a software workflow tool designed to aid the clinical assessment of adult Chest X-Ray cases with features suggestive of Pneumothorax in the medical care environment. HealthPNX analyzes cases using an artificial intelligence algorithm to identify suspected findings. It makes case-level output available to a PACS/workstation for worklist prioritization or triage. HealthPNX is not intended to direct attention to specific portions or anomalies of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out Pneumothorax or otherwise preclude clinical assessment of X-Ray cases.	Similar; different only in semantics but not substance.

	Subject	Predicate	Comparison
	out pneumothorax or otherwise preclude clinical assessment of X-Ray cases.		
Notification-only, parallel workflow tool	Yes	Yes	Identical
User	Radiologist	Radiologist	Identical
Radiological images format	DICOM	DICOM	Identical
Computational Platform	DrAid is designed as a software module that can be deployed on several computing and X-ray imaging platforms such as radiological imaging equipment, PACS, On Premise or On Cloud	HealthPNX is designed as a software module that can be deployed on PACS and Standalone desktop application, Zebra Worklist.	Similar
Alert to finding	Passive notification flagged for review	Passive notification flagged for review	Identical
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist	Identical
Artificial Intelligence algorithm	Yes	Yes	Identical
Limited to analysis of imaging data	Yes	Yes	Identical
Aids prompt identification of cases with indicated findings	Yes	Yes	Identical
Where results are received	PACS / Workstation	PACS / Workstation	Identical
Performance level – Timing of notification	Passive notification is visible upon transfer to the PACS with a delay of about 3.83 minutes for image transfer to the cloud, computation, and results transfer.	Passive notification is visible upon transfer to the PACS with a delay of about 22.1 seconds for image transfer to the cloud, computation, and results transfer.	Similar
Total Validation Data	Total: 850 chest X-ray cases	Total: 588 chest X-ray cases	Similar

	Subject	Predicate	Comparison
	Positive Pneumothorax: 354 cases Negative Pneumothorax: 496 cases	Positive Pneumothorax: 146 cases Negative Pneumothorax: 442 cases	
Performance	AUC: 96.10% (95% CI: [94.73, 97.30]) Sensitivity: 94.61% (95% CI: [92.16, 96.76]) Specificity:97.58% (95% CI: [96.36, 98.65])	AUC: 98.3% (95% CI: [97.40, 99.02]) Sensitivity: 93.15% (95% CI: [87.76%, 96.67%]) Specificity: 92.99% (95% CI: [90.19%, 95.19%])	Similar

The Indications for Use statement between the subject and predicate devices are equivalent. In addition, there are no differences that affect the safety and effectiveness of the subject device relative to the predicate; therefore, they can be considered substantially equivalent.

Software Verification and Validation:

Software verification and validation has been performed 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, and FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Training Data Set and Validation Data Set Separation

The data was intentionally managed to prevent overlap between training and validation data sets. For algorithm training, data from a hospital system in Vietnam and the publicly available CheXpert data set were utilized. For algorithm validation, the NIH Public data set and an additional Vietnamese data set were utilized. The two US data sets, CheXpert and the NIH Public data set are separate. Training and validation data from Vietnam come from separate hospitals and patient identification information was checked to confirm no patient overlap between the data sets. The data sets utilized to train and validate the algorithm are completely separate. See below for further breakdown of the data sets.

Performance Testing – Stand-Alone:

The performance of the DrAid™ for Radiology v1 device has been validated in two separate pivotal studies. The studies were conducted with chest x-ray data from the National Institute of

Health (NIH) and another from four Vietnamese hospitals.

The NIH data set was used to demonstrate the generalizability of the device to the demographics of the US population. The data set consisted of 565 radiographs with 386 negative and 179 positive pneumothorax cases. This data set was truthed by a panel of 3 US board certified radiologists. A table of the results is provided below:

Metrics	Mean	Standard Deviation	Upper 95% CI bound	Lower 95% CI bound
Sensitivity	0.9387	0.0180	0.9721	0.8994
Specificity	0.9947	0.0036	1.0000	0.9845
AUC	0.9667	0.0091	0.9834	0.9473

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

Characteristics	Quantity/Type
Number of Images	565
Number of Patients	565
Male	326
Female	239
Age (22 – 35)	102
Age (35-60)	295
Age (> 60)	168
Ethnicity	Representative of the US Population
View Position (AP)	380
View Position (PA)	185
Scanner Type	Unknown

Due to lack of scanner information from the NIH data set, a secondary data set from four Vietnamese hospitals (University Medical Center Hospital, Nam Dinh Lung Hospital, Hai Phong Lung Hospital, and Vinmec Hospital) was used to demonstrate the generalizability to different scanner types. This data set consisted of 285 radiographs with 110 negative and 175 positive pneumothorax cases. This data set was truthed by a panel of 3 US board certified radiologists. A table of the results is provided below:

Metrics	Mean	Standard Deviation	Upper 95% CI bound	Lower 95% CI bound
Sensitivity	0.9535	0.0160	0.9826	0.9186
Specificity	0.9464	0.0126	0.9687	0.9216
AUC	0.9500	0.0102	0.9691	0.9288

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

Characteristics	Quantity/Type
Number of Images	285
Number of Patients	285

Characteristics	Quantity/Type
Male	202
Female	83
Age (22 – 35)	52
Age (35-60)	102
Age (60-80)	131
Ethnicity	Vietnamese
Cannon (CXDI Control Software NE)	30
Siemens (Fluorospot Compact FD)	82
Conmed (Titan 2000)	22
GE (GE Healthcare)	151

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

Metrics	Mean	Standard Deviation	Upper 95% CI bound	Lower 95% CI bound
Sensitivity	0.9461	0.0117	0.9676	0.9216
Specificity	0.9758	0.0056	0.9865	0.9636
AUC	0.9610	0.0065	0.9730	0.9473

This performance is substantially equivalent to that of the predicate (K190362). A table of the predicate results is provided below:

Metrics	Mean	Upper 95% CI bound	Lower 95% CI bound
Sensitivity	93.15	87.76	96.67
Specificity	92.99	90.19	95.19
AUC	98.3	97.40	99.02

In addition, we assessed the performance time of the DrAid™ for Radiology v1 device that reflects the time it takes for the device to analyze the study and send a notification to the PACS worklist. The average performance time of the DrAid™ for Radiology v1 device was 3.83 minutes, a timing performance that is substantially equivalent to the predicate (22.1 seconds).

Conclusion:
The indications for use for DrAid™ for Radiology v1 are similar to the predicate device and differ only in semantics but not substance. In addition, there are no differences in technological characteristics that affect the safety and effectiveness of the subject device relative to the predicate. Furthermore, the performance testing results are similar to those of the predicate device and satisfy the requirements of the product code QFM. Therefore, it can be determined that the subject device and the predicate are substantially equivalent.