RADLogics, Inc.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LPP
555 13th Street NW
WASHINGTON DC 20004

April 8, 2020

Re: K193300
Trade/Device Name: AIMI-Triage CXR PTX
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: March 9, 2020
Received: March 9, 2020

Dear Dr. Smith:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K193300

Device Name

AIMI-Triage CXR PTX

Indications for Use *(Describe)*

The AIMI-Triage CXR PTX Application is a notification-only triage workflow tool for use by hospital networks and clinics to identify and help prioritize chest X-rays acquired in the acute setting for review by hospital radiologists. The device operates in parallel to and independent of standard of care image interpretation workflow. Specifically, the device uses an artificial intelligence algorithm to analyze images for features suggestive of moderate to large sized pneumothorax; it makes case-level output available to a PACS/workstation for worklist prioritization or triage. Identification of suspected cases of moderate to large sized pneumothorax is not for diagnostic use beyond notification.

The AIMI-Triage CXR PTX Application is limited to analysis of imaging data as a guide to possible urgency of adult chest X-ray image review, and should not be used in lieu of full patient evaluation or relied upon to make or confirm diagnoses. Notified radiologists are responsible for engaging in appropriate patient evaluation as per local hospital procedure before making care-related decisions or requests. The device does not replace review and diagnosis of the X-rays by radiologists. The device is not intended to be used with plain film X-rays.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB num

510(k) SUMMARY
K193300
RADLogics Inc.'s AIMI-Triage CXR PTX

Submitter

RADLogics Inc.
24 Westland Ave. #28
Boston, MA 02115

Phone: (408) 905-8054

Contact Person: Moshe Becker

Date Prepared: April 2, 2020

Name of Device: AIMI-Triage CXR PTX

Common or Usual Name: CADt software

Classification Name: Radiological computer-aided triage and notification software

Regulatory Class: II

Product Code: QFM

Predicate Device: Zebra Medical Vision Ltd.'s HealthPNX **(**K190362)

Device Description

The AIMI-Triage CXR PTX provides a chest X-ray prioritization service for use by radiologists to identify features suggestive of moderate to large sized pneumothorax. The artificial intelligence algorithm, trained via pattern recognition, processes each chest X-ray and flags those that appear to contain a moderate to large sized pneumothorax for urgent radiologist review. X-rays without an identified anomaly are placed in the worklist for routine review, which is the current standard of care. The user interface is minimal, consisting of the radiologist's existing picture archiving and communication system (PACS) viewer and worklist in which positively identified images are flagged by the software to notify of the suspected anomaly. Images are not marked or otherwise altered, and no diagnoses are provided.

The device does not have any direct accessories. However, it interacts with hospital communication and database systems in order to read and analyze cases in the worklist of the hospital's PACS system in order to identify suspected abnormal findings and transmit corresponding notifications to reflect its recommended prioritization of patient examinations for radiologist review. The software output is compatible with any PACS viewer and worklist.

Intended Use / Indications for Use

The AIMI-Triage CXR PTX Application is a notification-only triage workflow tool for use by hospital networks and clinics to identify and help prioritize chest X-rays acquired in the acute setting for

review by hospital radiologists. The device operates in parallel to and independent of standard of care image interpretation workflow. Specifically, the device uses an artificial intelligence algorithm to analyze images for features suggestive of moderate to large sized pneumothorax; it makes case-level output available to a PACS/workstation for worklist prioritization or triage. Identification of suspected cases of moderate to large sized pneumothorax is not for diagnostic use beyond notification.

The AIMI-Triage CXR PTX Application is limited to analysis of imaging data as a guide to possible urgency of adult chest X-ray image review, and should not be used in lieu of full patient evaluation or relied upon to make or confirm diagnoses. Notified radiologists are responsible for engaging in appropriate patient evaluation as per local hospital procedure before making care-related decisions or requests. The device does not replace review and diagnosis of the X-rays by radiologists. The device is not intended to be used with plain film X-rays.

Summary of Technological Characteristics

AIMI-Triage CXR PTX is technologically similar to the predicate device. Both are based on algorithms which have been trained to analyze images suggestive of pre-defined lung abnormalities and notify an appropriate clinician of these findings in parallel to standard of care image interpretation. The algorithms function similarly and with the same purpose of signaling potential pneumothorax without providing diagnosis or altering the original datasets. There are no notable technological differences between the subject and predicate devices. A table comparing the key features of the subject and predicate devices is provided in the substantial equivalence table below.

Performance Data

The AIMI-Triage CXR PTX was evaluated and verified in a blinded, retrospective and multi-center study for detecting pneumothorax in chest X-rays. A total of 300 frontal chest X-rays (PA/AP) were collected from US and OUS patients representative of the intended population. 168 (56%) were male with mean age 51.6 years and SD=18.6 (range 18-91), and 132 (44%) were female with mean age 51.8 and SD=16.2 (range 23-86).

The AIMI-Triage CXR PTX output was compared to the ground truth established by 3 independent US-board certified radiologists (Truthers). Each Truther involved in the ground truthing process was blinded to any other Truther's results, to any existing report, and to the results obtained by the AIMI-Triage CXR PTX software. Overall, the device was able to demonstrate an area under the curve (AUC) of 96.7% (95% CI: [95.0%, 98.4%]), which is substantially equivalent to the predicate device, and meets the required performance goal. The sensitivity and specificity of the device was 92% (95% CI: [86%, 96%]) and 90% (95% CI: [84%, 95%]), respectively.

In addition, the average time it takes the AIMI-Triage CXR PTX to analyze the study and send notification to the PACS worklist was measured to be 20.3 seconds, a timing performance that is substantially equivalent to the predicate (22.1 seconds). Lastly, device performance was evaluated by dataset/region and scanner spatial resolution as summarized in the tables below.

Device Performance by Dataset and Region

Category	N	Sensitivity	Specificity	AUROC
NIH (US)	147	97.6% (93.2,99.2)	90.8% (84.5,94.7)	0.987 (0.973,0.999)
PADCHEST (OUS)	153	85.3% (79.0,90.8)	89.7% (83.6,93.9)	0.949 (0.918,0.979)

Device Performance by Scanner Spatial Resolution

Spatial Resolution Category	N	Sensitivity	Specificity	AUROC
High range *<0.145* *(above 3.45 lp/mm)*	133	89.5% (83.0,94.1)	85.1% (77.7,90.6)	0.976 (0.944,0.999)
Mid range *0.145-0.170* *(2.95-3.45 lp/mm)*	88	92.6% (84.3,96.7)	93.4% (85.7,97.4)	0.983 (0.961,0.999)
Low range *>0.170* *(below 2.95 lp/mm)*	64	93.1% (84.8,98.3)	91.4% (80.7,96.5)	0.946 (0.911,0.980)

Thus, the device also performs comparably to the predicate in terms of time savings. The AIMI-Triage CXR PTX has a safety and effectiveness profile that is similar to the predicate device.

Conclusions

The AIMI-Triage CXR PTX has the same intended use and very similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the device's intended use and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the device and its predicate raise no new issues of safety or effectiveness. Performance data further demonstrate that the AIMI-Triage CXR PTX is as safe and effective as the HealthPNX (K190362). Thus, the subject device is substantially equivalent to the identified predicate.

Substantial Equivalence Table

	AIMI-Triage CXR PTX	HealthPNX (K190362)
Intended Use / Indications for Use	The AIMI-Triage CXR PTX Application is a notification-only triage workflow tool for use by hospital networks and clinics to identify and help prioritize chest X-rays acquired in the acute setting for review by hospital radiologists. The device operates in parallel to and independent of standard of care image interpretation workflow. Specifically, the device uses an artificial intelligence algorithm to analyze images for features suggestive of moderate to large sized pneumothorax; it makes case-level	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

	AIMI-Triage CXR PTX	HealthPNX (K190362)
	output available to a PACS/workstation for worklist prioritization or triage. Identification of suspected cases of moderate to large sized pneumothorax is not for diagnostic use beyond notification. The AIMI-Triage CXR PTX Application is limited to analysis of imaging data as a guide to possible urgency of adult chest X-ray image review, and should not be used in lieu of full patient evaluation or relied upon to make or confirm diagnoses. Notified radiologists are responsible for engaging in appropriate patient evaluation as per local hospital procedure before making care-related decisions or requests. The device does not replace review and diagnosis of the X-rays by radiologists. The device is not intended to be used with plain film X-rays.	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.
Classification	21 C.F.R. § 892,2080, Product Code QFM	
User	Radiologist	
Anatomical Region	Lung	
Clinical Condition	Pneumothorax	
Modality	Chest X-ray	
Segmentation of region of interest	No; device does not mark, highlight, or direct users' attention to a specific location in the original image	
Alteration of original image	No	
Relation to standard of care workflow	Independent/parallel; no cases are removed from worklist queue	
Algorithm	Artificial intelligence algorithm with database of images	
Notification / Prioritization	Yes	
Alert to Finding	Passive notification – flagged for review	
Where Results are Received	PACS / Workstation	