Zebra Medical Vision Ltd.
℅ Flair Bar
VP Operations
Shefayim Commercial Center, PO Box 25
Shefayim, 6099000
ISRAEL

May 6, 2019

Re: K190362
Trade/Device Name: HealthPNX
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer-aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: April 2, 2019
Received: April 5, 2019

Dear Flair Bar:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Office of In Vitro Diagnostics
and Radiological Health
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)*
K190362

Device Name
HealthPNX

Indications for Use *(Describe)*
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.

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.

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

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510 (k) Summary

510(K) Summary - HealthPNX
Zebra Medical Vision Ltd.

510(k) Number – K190362

I. Applicant's Name:

Zebra Medical Vision Ltd.
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Date Prepared: April 28, 2019

II. Device

Trade Name: HealthPNX

Classification Name:
Radiological Computer Aided Triage and Notification Software

Regulation Number:
21 CFR 892.2080

Classification:
Class II, Radiology

Product Code:
QFM

III. Predicate Device

The HealthPNX device is substantially equivalent to the following device:

Proprietary Name	cmTriage
Premarket Notification	K183285
Classification Name	Radiological Computer-Assisted Prioritization Software
Regulation Number	21 CFR 892.2080
Product Code	QFM
Regulatory Class	II

IV. Device Description:

Zebra's HealthPNX is a radiological computer-assisted triage and notification software system. The software automatically analyzes PA/AP chest x-rays and alerts the PACS/workstation once findings suspicious of pneumothorax are identified.

The following modules compose the HealthPNX software system:

Data input and validation: After a chest x-ray has been performed, a copy of the study is automatically retrieved and processed by the HealthPNX device. Following retrieval of a study, the validation feature assesses the input data (i.e. age, modality, view) to ensure compatibility for processing by the algorithm.
HealthPNX algorithm: Once a study has been validated, the algorithm analyzes the frontal chest x-ray for detection of suspected findings suggestive of pneumothorax.
IMA Integration feature: The study analysis and the results of a successful study analysis is provided to IMA, that notifies the PACS/workstation for prioritization through the worklist interface.
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.

The radiologist is then able to review the study earlier than in standard of care workflow.
In summary, the HealthPNX device is intended to provide a passive notification through the PACS/workstation to the radiologists indicating the existence of a case that may potentially benefit from the prioritization. It doesn't output an image and therefore it does not mark, highlight, or direct users' attention to a specific location on the original chest X ray.
The device aim is to aid in prioritization and triage of radiological medical images only.

V. Intended Use/Indication for Use

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.

VI. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics are compared below.

Technological Characteristics	HealthPNX	Predicate: cmTriage (K183285)	Similarities or Differences
Indication for use	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 of an image or to anomalies other than Pneumothorax. 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	cmTriage is a passive notification for prioritization-only, parallel-workflow software tool used by radiologists to prioritize specific patients within the standard-of-care image worklist for 2D FFDM screening mammograms. cmTriage uses 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. These flags are viewed by the radiologist via their Picture Archiving and Communication System (PACS) worklist. The decision to use cmTriage codes and how to use cmTriage codes is ultimately up to the radiologist. cmTriage does not send a proactive alert directly to the radiologist. Radiologists are responsible for reviewing each exam on a diagnostic viewer according to the current standard of care. cmTriage is limited to the categorization of exams, does not provide any diagnostic information beyond triage and prioritization, does not remove images from the radiologist's worklist, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis. cmTriage is for prescription use only.	Similar except to anatomy, imaging modality and lesion type
Notification-only, parallel workflow tool	Yes	Yes	Same
User	Radiologist	Radiologist	Same
Radiological images format	DICOM	DICOM	Same

Identify patients with prespecified clinical condition	Yes	Yes	Same
Clinical condition	Pneumothorax	Breast Cancer	Different but are "*time sensitive imaging*" per 21CFR 892.2080
Alert to finding	Passive notification flagged for review	Passive notification flagged for review	Same
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist	Same
Modality	X-Ray	FFDM screening mammograms	Different but both run on *"radiological medical images"* per 21 CFR 892.2080
Body part	Chest	Breast	Different anatomical sites but both *"operates on radiological images of the **human body**"* per 21 CFR 892.2080
Artificial Intelligence algorithm	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same
Aids prompt identification of cases with indicated findings	Yes	Yes	Same
Where results are received	PACS / Workstation	PACS / Workstation	Same

VII. Performance Data

The HealthPNX 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 HealthPNX device has been validated in a pivotal performance study that was carried out in the USA with simulated synthetic work-flow consisting of a truthed validation data-set. The data included a retrospective cohort of 588 anonymized Chest X-Ray cases from the USA and Israel, including pneumothorax positive (n=146) and negative cases (n=442), as well as

confounding imaging factors. The validation data set was truthed (ground truth) by three US Board Certified Radiologists (truthers). The stand-alone detection accuracy was measured on this cohort respective to ground truth. The triage effectiveness was evaluated by three different US Board Certified Radiologists (readers) that read these cases prospectively in real time with the HealthPNX device (HealthPNX prioritized work-list) and without (standard of care, "First-in-First-out" or "FIFO" queue) with a washout period separating between the two read periods with and without the HealthPNX device.

The detection accuracy met the a-priori performance goal (above 80% level of accuracy compared with ground truth). Overall, the HealthPNX was able to demonstrate an area under the curve (AUC) of 98.3% (95% CI: [97.40%, 99.02%]), which is substantially equivalent to the predicate device, and meets the required performance goal for QFM product code. Additionally, the overall agreement between HealthPNX device and ground truth was 93.03% (95% CI: [90.66%, 94.95%]). The sensitivity and specificity of the HealthPNX was 93.15% (95% CI: [87.76%, 96.67%]) and 92.99% (95% CI: [90.19%, 95.19%])(n=588), respectively.

The HealthPNX reduced triage time as compared to the standard of care (mean time 8.05 minutes (95% CI: [5.93, 10.16] minutes) vs. 68.98 minutes (95% CI: [60.53, 77.43] minutes)(n=588), with the HealthPNX compare to standard of care, respectively). This is a statistically significant reduction of triage time of time sensitive images. This establishes that the HealthPNX meets its intended use statement and is substantially equivalent to the predicate device.

In addition, we assessed the performance time of the HealthPNX 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 HealthPNX was 22.1 seconds, a timing performance that is substantially equivalent to the predicate (3.35 minutes).

VIII. Conclusion

The subject HealthPNX device and the cmTriage predicate device are both software-only devices intended to aid in triage of radiological images, independent of standard of care workflow. The labeling of both devices are limited to the categorization of exams and are not to be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

Both devices operate in parallel to the standard of care workflow in the sense that they do not change the original image, do not provide any marking, and do not remove cases from the standard of care. The minor differences between the subject device and the predicate raise no new issues of safety or effectiveness. In addition, performance testing demonstrates that the HealthPNX performs as intended . The HealthPNX device is therefore substantially equivalent to the cmTriage predicate.