Zebra Medical Vision Ltd.
% Shlomit Cymbalista
Head of Regulatory Affairs
Nano AI Ltd./Shefayim Commercial Center
PO Box 25
Sefayim, 6099000
ISRAEL

December 15, 2021

Re: K211803
Trade/Device Name: HealthPPT
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: November 7, 2021
Received: November 10, 2021

Dear Shlomit Cymbalista:

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)*
K211803

Device Name
HealthPPT

Indications for Use *(Describe)*
The HealthPPT device is a software workflow tool designed to aid the clinical assessment of adult frontal Chest X-Ray cases with features suggestive of pneumoperitoneum in the medical care environment. HealthPPT 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. HealthPPT is not intended to direct attention to anomalies other than pneumoperitoneum. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out pneumoperitoneum 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 - HealthPPT
Nanox AI Ltd.

510(k) Number – K211803

I. Applicant's Name:

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Fax: +972-9-8827795

Date Prepared: December 13, 2021

II. Device

Trade Name: HealthPPT

Classification Name:
QFM - Radiological Computer-Assisted Prioritization Software

Regulation Number:
892.2080

Classification:
Class II, Radiology

III. Predicate Device:

The HealthPPT device is substantially equivalent to the following device:

Proprietary Name	AIMI-Triage CXR PTX
Premarket Notification	K193300
Classification Name	Radiological Computer-Assisted Prioritization Software
Regulation Number	21 CFR 892.2080
Product Code	QFM
Regulatory Class	II

IV. Device Description

The HealthPPT solution is a software product that automatically identifies suspected findings on chest x-rays (e.g. pneumoperitoneum) and notifies PACS/workstation of the presence of this critical finding in the scan. This notification allows for prioritization of the identified scan and assists clinicians in viewing the prioritized scan before others. The device aim is to aid in prioritization and triage of radiological medical images only.

The software is automatic and is capable of analyzing PA or AP chest x-rays. If a suspected finding is found in a scan, the alert is automatically sent to the PACS/workstation used by the radiologist or to a standalone desktop application in parallel with the ongoing standard of care. The PACS/workstation prioritizes and displays the study through its worklist interface. The ZebrAInsight standalone application includes a compressed preview image meant for informational purposes only and is not intended for diagnostic use.

The HealthPPT 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 HealthPPT device. The device performs the analysis of the study and returns a notification about the relevant pathology to the PACS/workstation for prioritization. The clinician is then able to review the study earlier than in standard of care workflow.

The software does not recommend treatment or provide a diagnosis. It is meant as a tool to assist in improved workload prioritization of critical cases. The final diagnosis is provided by a radiologist after reviewing the scan itself.

The following modules compose the HealthPPT software for Pneumoperitoneum:

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.

Pneumoperitoneum algorithm: Once a study has been validated, the algorithm analyzes the frontal chest x-ray for detection of suspected finding suggestive of pneumoperitoneum.

IMA Integration feature: The study analysis and the results of a successful study analysis is provided to IMA, to then be sent to the PACS/workstation for prioritization.

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.

V. Intended Use/Indication for Use:

The Zebra HealthPPT device is a software workflow tool designed to aid the clinical assessment of adult frontal Chest X-Ray cases with features suggestive of pneumoperitoneum in the medical care environment. HealthPPT 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. HealthPPT is not intended to direct attention to anomalies other than pneumoperitoneum. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. Its results are not intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out pneumoperitoneum or otherwise preclude clinical assessment of X-Ray cases.

VI. 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 HealthPPT 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 HealthPPT**	**Predicate Device AIMI-Triage CXR PTX (K193300)**	**Summary**
Indication for Use/Intended Use	The Zebra HealthPPT device is a software workflow tool designed to aid the clinical assessment of adult frontal Chest X-Ray cases with features suggestive of pneumoperitoneum in the medical care environment. HealthPPT 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. HealthPPT is not intended to direct attention to anomalies other than pneumoperitoneum. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. Its results are not	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 caselevel 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	Similar expect for lesion type

	intended to be used on a stand-alone basis for clinical decision-making nor is it intended to rule out pneumoperitoneum or otherwise preclude clinical assessment of X-Ray cases.	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.	
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	Pneumoperitoneum	Pneumothorax	Different but as per the product classification definition, both identify "*time sensitive imaging*."
Alert to finding	Yes; notification flagged for review on hospital worklist or Zebra application	Yes; notification flagged for review	Similar, HealthPPT can be directly integrated for notification on the hospital worklist or on the Zebra application. Both notifications operate in parallel

			with the standard of care.
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist	Same
Modality	Chest X-Ray	Chest X-Ray	Same
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
Preview Image	Presentation of a compressed preview image for initial assessment, not meant for diagnostic purposes. The device operated in parallel with the standard of care, which remains the default option for all cases.	Presentation of notification 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.	Similar, HealthPPT provides an additional compressed image as a preview only, not for diagnostic use.
Multiple operating points	Yes; 2 optional operating points	No; single operating point	Different, but all operating points comply with DEN 170073 Special control 1(iii).
Where results are received	PACS / Workstation	PACS / Workstation	Same

VII. Performance Data:

Safety and performance of HealthPPT 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 HealthPPT device has been validated in a performance study for triage of time sensitive chest X-Ray cases. The data included a retrospective cohort of 216 anonymized Chest X-ray cases from the USA and OUS, including 107 cases positive for Pneumoperitoneum and 109 cases negative for Pneumoperitoneum, 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 the ground truth.

The HealthPPT device detection accuracy met the accuracy performance goals for AUC, and the sensitivity, and specificity for two defined operating points. Overall, the HealthPPT was able to demonstrate an area under the curve (AUC) of 96.75% (95% CI: [94.28%, 99.21%]), which is both comparable to the predicate device, and exceeds the required technical method under the QFM product code. The sensitivity and specificity of the HealthPPT was reported for two operating points. The first **"**balanced sensitivity and specificity" (default) operating point demonstrated a sensitivity of 92.52% (95% CI: [85.94%;96.16%]) and a specificity of 92.66% (95% CI: [86.18%;96.23%]). The second "high-specificity" operating point reported a sensitivity of 80.37% (95% CI: [71.85%;86.79%]) and a specificity of 97.25% (95% CI: [92.22%;99.06%]). Both operating points reached their performance goal.

In addition, we assessed the time it takes for the HealthPPT device to analyze the study and send a result. The average performance time of the HealthPPT was 4.78 seconds, which is significantly lower than the time reported by the predicate device (20.3 seconds).

VIII. Conclusion

The subject HealthPPT device and the AIMI-Triage CXR PTX (K193300) predicate device are both software-only devices intended to aid in triage of radiological images, independent of and in parallel to the standard of care workflow. Both devices incorporate an artificial intelligence algorithm. 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 HealthPPT performs as intended. The HealthPPT device is therefore substantially equivalent to the AIMI-Triage CXR PTX predicate.