Quanta Computer Inc.
℅ Joe Wang
Research Specialist
No. 188, Wenhua 2nd Rd., Guishan Dist.
Taoyuan City, 33383
TAIWAN

January 27, 2023

Re: K221868
Trade/Device Name: QOCA® image Smart CXR Image Processing System
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: December 9, 2022
Received: December 19, 2022

Dear Joe Wang:

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
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Supplement 4

Section 4 - Indications for Use Statement

(Form FDA 3881)

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)*
K221868

Device Name
QOCA® image Smart CXR Image Processing System

Indications for Use *(Describe)*
QOCA® image Smart CXR Image Processing System is a software as medical device (SaMD) used, through artificial intelligence/deep learning technology, to analyze chest X-ray images of adult patient, and then identify cases with suspected pneumothorax. This product shall be used in conjunction with Picture Archiving and Communication System (PACS) at the hospital. This product will automatically analyze the DICOM files automatically pushed from PACS, and then make a notation next to the cases with suspected pneumothorax. This product is only used to remind radiologists to prioritize reviewing cases with suspected pneumothorax. Its results cannot be used as a substitute for a diagnosis by a radiologist, nor can it be used on a stand-alone basis for clinical decision-making.

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.

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 number."

Supplement 5

Section 5 - 510(k) Summary

510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: 01/19/2023

5.3 Submitter:

Address:	Quanta Computer Inc. No. 188, Wenhua 2nd Rd., Guishan Dist., Taoyuan City 33383, Taiwan (R.O.C)
Phone:	+886-3-327-2345
Contact:	Joe Wang joe_wang@quantatw.com

5.4 Identification of the Device:

Proprietary/Trade Name:	QOCA® image Smart CXR Image Processing System
Model Number:	ZSWC001
Regulation Description:	Radiological Computer-Assisted Prioritization Software For Lesions
Review Panel:	Radiology
Regulation Number:	892.2080
Product Code:	QFM
Device Class:	II

5.5 Identification of the Predicate Device:

Predicate Device Name:	HealthPNX
Model Number:	—
510(k) Number:	K190362
Manufacturer:	Zebra Medical Vision Ltd.
Regulation Number:	892.2080
Product Code:	QFM
Device Class:	II

5.6 Intended Use/Indications for Use of the Device

QOCA® image Smart CXR Image Processing System is a software as medical device (SaMD) used, through artificial intelligence/deep learning technology, to analyze chest X-ray images of adult patient, and then identify cases with suspected pneumothorax. This product shall be used in conjunction with Picture Archiving and Communication System (PACS) at the hospital. This product will automatically analyze the DICOM files automatically pushed from PACS, and then make a notation next to the cases with suspected pneumothorax. This product is only used to remind radiologists to prioritize reviewing cases with suspected pneumothorax. Its results cannot be used as a substitute for a diagnosis by a radiologist, nor can it be used on a stand-alone basis for clinical decision-making.

5.7 Device Description

This product, QOCA® image Smart CXR Image Processing System, is a web-based medical device using a locked artificial intelligence algorithm. It provides features such as cases sorting and image viewing, and supports multiple users at a time.

After connecting to Picture Archiving and Communication System (PACS) at the hospital, this product is capable of automatically analyzing either posteroanterior (PA) view or anteroposterior (AP) erect view chest X-ray images automatically pushed from PACS. Once a case with suspected pneumothorax is identified, a notation will be made next to the case in question, so the radiologist can prioritize to review cases with suspected pneumothorax in the Viewer Page. This product will not directly indicate, however, the specific portions or anomalies on the image.

Bases on the results of the standalone performance assessment, this product achieves, identification accuracy of $AUC > 95\%$ with $Sensitivity > 91\%$ and $Specificity > 92\%$.

The dataset used for training the algorithm was independent of the testing dataset. The training dataset included various characteristics, such as age, gender, radiographic positioning, radiography device, etc.

5.8 Comparison of Technological Characteristics with the Predicate Device

QOCA® image Smart CXR Image Processing System submitted in this 510(k) file is substantially equivalent in intended use, safety and performance to the cleared HealthPNX (K190362). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
510(k) No.	K221868	K190362	—
Proprietary Name	QOCA® image Smart CXR Image Processing System	HealthPNX	—
Manufacturer	Quanta Computer Inc.	Zebra Medical Vision Ltd.	—
Regulation Number	21 CFR 892.2080	21 CFR 892.2080	***Same***
Product Code	QFM	QFM	***Same***
Classification	Class II	Class II	***Same***
Intended Use	QOCA® image Smart CXR Image Processing System is a software as medical device (SaMD) used, through artificial intelligence/deep learning technology, to analyze chest X-ray images of adult patient, and then identify cases with suspected pneumothorax. This product shall be used in conjunction with Picture Archiving and Communication System (PACS) at the hospital. This product will automatically analyze the DICOM files	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	***Similar*** Both devices are intended to aid in worklist triage by providing notification of suspected pneumothorax cases using an artificial intelligence algorithm. They are not intended to be used on a stand-alone basis for clinical decision-making or clinical diagnosis.

Item	Subject device	Predicate device	Substantial equivalence determination
	automatically pushed from PACS, and then make a notation next to the cases with suspected pneumothorax. This product is only used to remind radiologists to prioritize reviewing cases with suspected pneumothorax. Its results cannot be used as a substitute for a diagnosis by a radiologist, nor can it be used on a stand-alone basis for clinical decision-making.	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	
Notification-only, parallel workflow tool	Yes	Yes	***Same***
User	Radiologist	Radiologist	***Same***
Radiological image format	DICOM	DICOM	***Same***
Identify patients with prespecified clinical condition	Yes	Yes	***Same***
Clinical condition	Pheumothorax	Pheumothorax	***Same***
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	X-Ray	***Same***
Body part	Chest	Chest	***Same***

Item	Subject device	Predicate device	Substantial equivalence determination
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	Workstation	PACS/Workstation	***Similar*** The subject device will be connected with PACS and receives patients' chest X-ray images. The results will only be presented on the workstation. It will not raise any new issues of safety or efficacy.
Time-to-notification	The average performance time is 4.94 seconds.	The average performance time is 22.1 seconds.	***Same*** Both devices can provide effective triage.

Similarity and Difference

The subject device has the similar intended use to the predicate device. Both devices are intended to aid in worklist triage by providing notification of suspected pneumothorax cases using an artificial intelligence algorithm. And they are not intended to be used on a stand-alone basis for clinical decision-making or clinical diagnosis.

The slight difference between the subject device and the predicate is the result presentation. However, the result presenting of the subject device is within the scope of the predicate. Therefore, it will not affect the substantial equivalence.

5.9 Performance Data

The subject product, QOCA® image Smart CXR Image Processing System has been evaluated and verified in accordance with software specifications and applicable performance standards to ensure performance.

The separation of the model training dataset and performance assessment dataset

We split dataset into two parts: a model training dataset and a performance assessment dataset. The training dataset is used to train the model, and divided into three sets: the training set, the validation set, and the test set. The performance assessment dataset is used to valid the model's performance. By using a separate performance assessment dataset, we can get a better idea of how well the model will perform in the real world.

All data was carefully managed to prevent overlap and ensure that each dataset was completely independent by using accession numbers and patient IDs. The model training dataset was collected from two hospitals, and additional data from the US National Institutes of Health (NIH) was added to the test set to improve its US patient population representativeness during training. For performance assessment, the US patient population data form MIMIC dataset and a medical institution independent of model training dataset were used. This helped us get a better idea of how well the model would perform in the real world. To avoid any potential biases,

the data for the model training dataset and the performance assessment dataset were carefully chosen and separated.

Performance assessment

The performance of the subject device, QOCA® image Smart CXR Image Processing System, has been validated in two separate pivotal studies. The two studies were performed with the data from the MIMIC dataset and a Taiwanese hospital respectively. The performance of the subject device across the performance assessment dataset achieves an area under the curve (AUC) of 97.8% (95% CI: [97.0%, 98.5%]; in addition, the sensitivity and specificity achieves 92.5% (95% CI: [90.5%, 94.2%]), 94.0% (95% CI: [93.9%, 94.6%]) respectively, without subgroup breakdown. This performance is substantially equivalent to the predicate device (K190362); AUC of 98.3% (95% CI: [97.40%, 99.02%]), the sensitivity and specificity is 93.15% (95% CI: [87.76%, 96.67%]) and 92.99% (95% CI: [90.19%, 95.19%]), respectively.

First, the MIMIC dataset was used to demonstrate the generalizability of the device to the demographics of the US population. The dataset consisted of 3,105 radiographs with 336 positive and 2,769 negative pneumothorax cases. The ethnicities included Asian, Black/African American, Hispanic or Latino, and White. The dataset was truthed by three radiologists. The performance of the subject device to the MIMIC dataset is AUC of 97.7% (95% CI: [96.5%, 98.8%]), the sensitivity and specificity is 93.7% (95% CI: [90.6%, 96.0%]) and 93.3% (95% CI: [92.3%, 94.2%]), respectively.

The characteristics of the MIMIC dataset summarizes in below table:

Characteristics	Subset	Quantity
Age	22 ≤ age < 65	2,449
	65 ≤ age	656
Gender	Male	1,516
	Female	1,589
Radiographic positioning	PA view	2,272
	AP erect view	24

Characteristics	Subset	Quantity
	Supine view	809
Race and ethnicity	Asian	200
	Black/African American	402
	Hispanic or Latino	598
	White	1,905

Second, the additional Taiwanese dataset was used to demonstrate the generalizability to different imaging equipment. The dataset consisted of 2,947 radiographs with 472 positive and 2,475 negative pneumothorax cases. The dataset was truthed by three radiologists. The performance of the subject device to the Taiwanese dataset is AUC of 97.4% (95% CI: [96.9%, 98.7%]), the sensitivity and specificity is 91.7% (95% CI: [88.8%, 94.0%]) and 94.9% (95% CI: [93.9%, 95.7%]), respectively.

The characteristics of the Taiwanese dataset summarizes in below table:

Characteristics	Subset	Quantity
Age	$22 \leq age < 65$	2,697
	$65 \leq age$	250
Gender	Male	1,262
	Female	1,685
Radiographic positioning	PA view	501
	AP erect view	1,431
	Supine view	1,015
Race and ethnicity	Taiwan population	2,947
Imaging equipment	MRAD-A50S	287
	MRAD-A80S	185

Besides, we assessed the performance time of the subject device that reflects the time it takes for the device to analyze the study and send a notification to the worklist. The average performance time of the subject device was 4.94 seconds, and that is substantially equivalent to the predicate (22.1 seconds).

5.10 Conclusion

The subject device has a similar intended use to the predicate device, and the slight difference does not affect the substantial equivalence. In addition, there are no differences in technological characteristics that affect the safety and effectiveness of the subject device relative to the predicate. Moreover, the performance testing results are similar to the predicate device. Therefore, the subject device, QOCA® image Smart CXR Image Processing System, is substantially equivalent to the predicate device.