GE Medical Systems, LLC.
% Camille Vidal
Director of Regulatory Affairs Strategy
3000 N. Grandview Blvd.
WAUKESHA WI 53188

August 12, 2019

Re: K183182
Trade/Device Name: Critical Care Suite
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: July 12, 2019
Received: July 12, 2019

Dear Camille Vidal:

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)*
K183182

Device Name
Critical Care Suite

Indications for Use *(Describe)*
Critical Care Suite is a computer aided triage and notification device that analyzes frontal chest x-ray images for the presence of prespecified critical findings (pneumothorax). Critical Care Suite identifies images with critical findings to enable case prioritization or triage in the PACS/workstation.

Critical Care Suite is intended for notification only and does not provide diagnostic information beyond the notification. Critical Care Suite should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. It is not intended to replace the review of the x-ray image by a qualified physician.

Critical Care Suite is indicated for adult-size patients.

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
K183182

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	August 7th, 2019
Submitter:	GE Medical Systems, LLC 3000 N. Grandview Blvd Waukesha, WI 53188, USA
Primary Contact Person:	Camille Vidal Director of Regulatory Affairs Strategy GE Healthcare 240-280-5356 Camille.Vidal@ge.com
Secondary Contact Person:	Diane Uriell Regulatory Affairs Director GE Healthcare 262-290-8218 Diane.Uriell@ge.com
Device Trade Name:	Critical Care Suite
Common/Usual Name:	Radiological Computer Assisted Triage and Notification Software
Classification Names: Product Code:	Class II, Radiological Computer Assisted Triage and Notification Software, 21 CFR 892.2080 QFM
Predicate Device(s):	HealthPNX by Zebra Medical Vision, K190362 Class II, 21 CFR 892.2080, Product code: QFM

Indications for use	Critical Care Suite is a computer aided triage and notification device that analyzes frontal chest x-ray images for the presence of prespecified critical findings (pneumothorax). Critical Care Suite identifies images with critical findings to enable case prioritization or triage in the PACS/workstation. Critical Care Suite is intended for notification only and does not provide diagnostic information beyond the notification. Critical Care Suite should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. It is not intended to replace the review of the x-ray image by a qualified physician. Critical Care Suite is indicated for adult-size patients.
Device Description:	Critical Care Suite is a software module that employs AI-based image analysis algorithms to identify pre-specified critical findings (pneumothorax) in frontal chest X-ray images and flag the images in the PACS/workstation to enable prioritized review by the radiologist. Critical Care Suite employs a sequence of vendor and system agnostic AI algorithms to ensure that the input images are suitable for the pneumothorax detection algorithm and to detect the presence of pneumothorax in frontal chest X-rays: - The Quality Care Suite algorithms conduct an automated check to confirm that the input image is compatible with the pneumothorax detection algorithm and that the lung field coverage is adequate; - the PTX Classifier determines whether a pneumothorax is present in the image. If a pneumothorax is detected, Critical Care Suite enables case prioritization or triage through direct communication of the Critical Care Suite notification during image transfer to the PACS. It can also produce a Secondary Capture DICOM Image that presents the AI results to the radiologist. When deployed on a Digital Projection Radiographic Systems such as Optima XR240amx, Critical Care Suite is automatically run after image acquisition. Quality Care Suite algorithms produce an on-device notification if the lung field has atypical positioning to give the

	technologist the opportunity to make correction before sending the image to the PACS. The Critical Care Suite output is then sent directly to PACS upon exam closure where images with a suspicious finding are flagged for prioritized review by the Radiologist. In parallel, an on-device, technologist notification is generated 15 minutes after exam closure, indicating which cases were prioritized by Critical Care Suite in PACS. The technologist notification is contextual and does not provide any diagnostic information. The on-device, technologist notification is not intended to inform any clinical decision, prioritization, or action. The Digital Projection Radiographic System intended use remains unchanged in that the system is used for general purpose diagnostic radiographic imaging.

Predicate Device Comparison	Critical Care Suite	HealthPNX (K190362)
Device classification	Radiological Computer Assisted Triage and Notification software, Class II, QFM	Radiological Computer Assisted Triage and Notification software, Class II, QFM
Targeted clinical condition, anatomy and modality	Pneumothorax Chest/Lung Frontal Chest X-ray	Pneumothorax Chest/Lung Chest X-ray
Input Validation	Quality Care Suite algorithms conduct an automated check to confirm image is compatible with processing algorithm (age, frontal chest, lung field) Atypical lung field positioning generates notifications on the X-ray system and Secondary Capture DICOM Image when generated.	Validation feature of HealthPNX verifies that input age, modality and view to ensure compatibility with processing algorithm. In case of failure during data validation, system outputs an error code.
Algorithm for Pneumothorax detection	AI algorithm designed to detect pneumothorax in frontal chest X-ray images Critical Care Suite uses a vendor agnostic algorithm compatible with DICOM frontal chest X-ray images acquired on fixed or mobile systems.	AI algorithm designed to detect pneumothorax in chest X-ray images. HealthPNX employs a vendor agnostic algorithm compatible with DICOM chest X-ray images.
Computational Platform	Critical Care Suite is designed as a software module that can be deployed on several computing and X-ray imaging platforms such as Digital Projection Radiographic Systems, PACS, On Premise or On Cloud.	Cloud-based computation upon transfer to PACS of image

Predicate Device Comparison	Critical Care Suite	HealthPNX (K190362)
	It processes images within seconds of image acquisition when deployed on Digital Projection Radiographic Systems.	
Device output in case of positive detection	Critical Care Suite enables case prioritization or triage through direct communication of the Critical Care Suite notification during image transfer to the PACS. No markup on original image Upon image acquisition on a Digital Projection Radiographic System, an on-device, technologist notification is generated 15 minutes after exam closure, indicating which cases were prioritized by Critical Care Suite in PACS. The technologist notification is contextual and does not provide any diagnostic information. The on-device, technologist notification is not intended to inform any clinical decision, prioritization, or action.	Integration module notifies the PACS/workstation for prioritization through the worklist interface. No markup on original image
Notification: Recipient, timing and means of notification	Passive notification to radiologist. Images with suspicion of pneumothorax are flagged in PACS/workstation.	Passive notification to radiologist. Images with suspicion of pneumothorax are flagged in PACS/workstation.
Performance level – timing of notification	Exams arrive on PACS with the passive notification already incorporated, therefore there is no delay for image transfer or computation. The worklist prioritization happens immediately once the exam is received on the PACS.	Passive notification is visible upon transfer to the PACS with a delay of about 22 seconds for image transfer to the cloud, computation and results transfer.
Performance level – accuracy of classification	ROC AUC > 0.95 AUC: 0.9607 (95% CI [0.9491, 0.9724]) Specificity 93.5% (95% CI [91.1%, 95.8%]) Sensitivity 84.3% (95% CI [80.6%, 88.0%]) AUC on large pneumothorax 0.9888 (95% CI [0.9810, 0.9965]) Sensitivity on large pneumothorax 96.3% (95% CI [93.3%, 99.2%] AUC on small pneumothorax 0.9389 (95% CI [0.9209, 0.9570]) Sensitivity on small pneumothorax 75% (95% CI [69.2%, 80.8%])	ROC AUC > 0.95 AUC: 0.983 (95% CI [0.9740, 0.9902]), Specificity: 93% Sensitivity: 93% Stratified results on small vs. large pneumothorax not assessed.

Clinical and Non-Clinical Tests	**Summary of Non-Clinical Tests:** Critical Care Suite contains a set of AI algorithms that resides within a software module that has been designed to be integrated within several computing and imaging platforms, such as the Optima XR240amx.

	The following quality assurance measures were applied to the development of Critical Care Suite and deployment onto the Optima XR240amx system: ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Testing on unit level (Module verification) ▪ Integration testing (System verification) ▪ Performance testing (Verification) ▪ Safety testing (Verification) ▪ Simulated use testing (Validation) Critical Care Suite specific verification was conducted to demonstrate proper implementation of Critical Care Suite software design requirements. Regression testing of the Optima XR 240amx feature functionality was conducted to verify proper integration of the Critical Care Suite into the Optima XR240amx software and device. Validation was performed on Optima XR240amx with integrated Critical Care Suite. The test plans have been executed with acceptable results. **Timing Performance** Internal bench testing was conducted with and without Critical Care Suite integrated within the Optima XR240amx. The average time to acquire, annotate, process and transfer an image from the x-ray system to PACS was measured and found to take 42 seconds on average. Whether Critical Care Suite was on or off did not make a statistical difference in the timing. This shows that Critical Care Suite has no timing impact on image acquisition, processing, annotation and transfer to PACS as compared to standard of care when measured in the same conditions. Since the image arrives on PACS with the passive notification already incorporated, the worklist prioritization happens immediately once the image is received on the PACS.

	The timing of the processing and prioritization is well within the clinical operational expectations of standard chest radiographic exam and its reading by radiologists. According to *Gaskin, Cree M., et al. "Impact of a Reading Priority Scoring System on the Prioritization of Examination Interpretations." American Journal of Roentgenology 206.5 (2016): 1031-1039* and *Rachh, Pratik, et al. "Reducing STAT Portable Chest Radiograph Turnaround Times: A Pilot Study." Current problems in diagnostic radiology (2017),* the estimated average Report Turnaround Time for non-prioritized or ineffectively prioritized exams is between 7.23 hours and 8.67 hours. Incorporating the Critical Care Suite passive notification to help radiologists prioritize their exam reads would drastically reduce this turnaround time for the cases that have been flagged by Critical Care Suite as compared to standard of care (First-In, First-Out). **Summary of Clinical Evaluation:** Critical Care Suite was evaluated on a dataset of 804 frontal chest X-rays collected in North America and representative of the intended population. The algorithm prediction is compared to the ground truth established by 3 independent US-board certified radiologists. The algorithm ROC AUC meets the performance requirement of FDA product code QFM (AUC>95%): AUC=96% (95% CI [94.9% - 97.2%]) (PTX present: N=376; PTX absent: N=428). Stratified analyses showed consistent performance across image view (AP/PA), system manufacturer (GE/non-GE) and data sources. Critical Care Suite performs at high specificity 93.5% (95% CI [91.1% - 95.8%]) and high sensitivity 84.3% (95% CI [80.6% – 88.0%]). Stratified analysis by pneumothorax size shows that nearly all large pneumothoraces are detected (96.3% with 95% CI [93.3% - 99.2%]) while 3 out 4 small pneumothoraces are detected (75% with 95% CI [69.2% - 80.8%]) with limited false notifications thanks to the high specificity.
Substantial Equivalence Discussion:	Critical Care Suite and HealthPNX are software devices intended to aid in triage and prioritization of radiological images. Both devices use artificial intelligence algorithms to identify suspicious findings suggestive of pneumothorax in chest X-ray images. Both devices are intended to

	notify the radiologist by producing a passive notification in the form of a case level flag in the PACS/workstation. Critical Care Suite, when deployed on a Digital Projection Radiographic System, generates an on-device, technologist notification 15 minutes after exam closure, indicating which cases were prioritized by Critical Care Suite in PACS. The technologist notification is contextual and does not provide any diagnostic information. The on-device, technologist notification is not intended to inform any clinical decision, prioritization, or action. The predicate and proposed devices use similar artificial intelligence techniques to process radiological images. Specifically, the proposed and predicate software utilize a deep learning algorithm trained on annotated medical images. Both trained algorithms achieve the high accuracy performance requirement for product code QFM (ROC AUC >0.95) in the detection of pneumothorax in a representative image dataset withheld for testing. Critical Care Suite and HealthPNX operates at high specificity and high sensitivity. Critical Care Suite was shown to have no impact on timing of image acquisition, processing, annotation and transfer to PACS as compared to standard of care. Exams arrive on PACS with the passive notification already incorporated, therefore there is no delay for image transfer or computation. The worklist prioritization happens immediately once the exam is received on the PACS. In comparison, HealthPNX, reports a delay of about 22 seconds for results to appear in the PACS worklist. The differences between Critical Care Suite and HealthPNX do not raise new type of safety and effectiveness question. Non-clinical and clinical testing shows that Critical Care Suite delivers effective triage by accurately detecting cases with pneumothorax and generating a passive notification in the PACS/workstation as soon as the image is available for review in the PACS. Radiologists can easily identify images that will benefit from prioritized review, leading to reduced turn-around time. Critical Care Suite was found to be substantially equivalent to HealthPNX.