GE Medical Systems, LLC
℅ Chris Paulik
Regulatory Affairs Manager
3000 N. Grandview Blvd.
WAUKESHA WI 53188

May 25, 2023

Re: K223491
Trade/Device Name: Critical Care Suite with Pneumothorax Detection AI Algorithm
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QBS
Dated: April 26, 2023
Received: April 27, 2023

Dear Chris Paulik:

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 Team
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

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)*

K223491

Device Name

Critical Care Suite with Pneumothorax Detection AI Algorithm

Indications for Use *(Describe)*

Critical Care Suite with Pneumothorax Detection AI Algorithm is a computer-aided triage, notification, and diagnostic device that analyzes frontal chest X-ray images for the presence of a pneumothorax. Critical Care Suite identifies and highlights images with a pneumothorax to enable case prioritization or triage and assist as a concurrent reading aide during interpretation of radiographs.

Intended users include qualified independently licensed healthcare professionals (HCPs) trained to independently assess the presence of pneumothoraxes in radiographic images and radiologists.

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 adults and Transitional Adolescents (18 to < 22 years old but treated like adults).

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.

510(k) Summary

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

Date:	May 25, 2023
Submitter:	GE HealthCare, (GE Medical Systems, LLC) 3000 N. Grandview Blvd Waukesha, WI 53188 USA
Primary Contact Person:	Chris Paulik Senior Regulatory Affairs Manager GE HealthCare 262-894-5415 Christopher.A.Paulik@ge.com
Secondary Contact Person:	Gregory Pessato Regulatory Affairs Director GE HealthCare +33 (6) 34423240 GregoryPessato@ge.com
Device Trade Name:	Critical Care Suite with Pneumothorax Detection AI Algorithm
Common / Usual Name:	Radiological computer assisted detection and diagnosis software
Classification Names and Product Code:	Regulation Name: Radiological computer assisted detection and diagnosis software Regulation: 21 CFR 892.2090 Classification: Class II Product Codes: QBS
Predicate Device:	BoneView (K212365) Regulation Name: Radiological computer assisted detection and diagnosis software Regulation: 21 CFR 892.2090 Classification: Class II

	Product Codes: QBS
Reference Device:	Critical Care Suite (K183182) Regulation Name: Radiological computer aided triage and notification software Regulation: 21 CFR 892.2080 Classification: Class II Product Codes: QFM
Device Description:	Critical Care Suite is a suite of AI algorithms for the automated image analysis of frontal chest X-rays acquired on a digital x-ray system for the presence of critical findings. Critical Care Suite with Pneumothorax Detection AI Algorithm is indicated for adults and transitional adolescents (18 to <22 years old but treated like adults) and is intended to be used by licensed qualified healthcare professionals (HCPs) trained to independently assess the presence of pneumothoraxes in radiographic images and radiologists. Critical Care Suite is a software module that can be deployed on several computing platforms such as PACS, On Premise, On Cloud or X-ray Imaging Systems. Today's clinical workflow, hospitals are overburdened by large volume of orders and long turnaround times for radiologist reports. Critical Care Suite with the Pneumothorax Detection AI Algorithm enables effective prioritization and assists in the detection / diagnosis of pneumothoraxes for radiologists and HCPs that have been trained to independently assess the presence of pneumothoraxes in radiographic images. It performs this task by flagging images with a suspicious finding and providing a localization overlay of the suspected pneumothorax as well as a graphical representation of the algorithm's confidence in the resultant finding. These outputs can be displayed wherever the reviewing physician normally conducts their reads per their standard of care, including PACS, On Premise, On Cloud and Digital Projection Radiographic Systems.
Intended Use:	Critical Care Suite with Pneumothorax Detection AI Algorithm is intended to aide a clinician in the detection and localization of a pneumothorax on frontal chest radiographic images.
Indications for Use:	Critical Care Suite with Pneumothorax Detection AI Algorithm is a computer-aided triage, notification, and diagnostic device that analyzes frontal chest X-ray images for the presence of a pneumothorax. Critical Care Suite identifies and highlights images with a pneumothorax to enable case prioritization or triage and assist as a concurrent reading aid during interpretation of radiographs. Intended users include qualified independently licensed healthcare professionals (HCPs) trained to independently assess the presence of pneumothoraxes in radiographic images and radiologists. 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 adults and Transitional Adolescents (18 to <22 years old but treated like adults).
Technology:	Critical Care Suite with Pneumothorax Detection AI Algorithm employs the same fundamental scientific technology as its predicate and reference devices. They are all deep learning locked AI algorithms that can be deployed on several computing platforms such as PACS, On Premise, On Cloud or X-ray Imaging Systems. The patient and user populations are equivalent to what was provided with Critical Care Suite with Pneumothorax Detection AI Algorithm. The output is equivalent since both predicate and proposed devices produce a result if a suspicious finding is detected, provide a localization overlay of the suspected pathology within the image and a representation of the algorithm's confidence in the resultant finding. The intended use has been expanded from the original release of Critical Care Suite (K183182) to display an overlay to the reviewing physician that helps localize a detected pneumothorax. It also provides a confidence level to the reviewing physician that provides contextual information in the algorithm's confidence for its pneumothorax detection output. The differences between Critical Care Suite with Pneumothorax Detection AI Algorithm and BoneView are the specific pathologies that are being detected. Critical Care Suite with Pneumothorax Detection AI Algorithm analyzes frontal chest radiographic images for the presence of a suspected pneumothorax where BoneView analyzes radiographic images for the presence of suspected fractures. This difference does not impact the safety or efficacy of Critical Care Suite with Pneumothorax Detection AI Algorithm since both devices analyze images using deep learning AI technology to detect pathologies producing an output that can aide clinicians and radiologists with their diagnosis.

Product Device Comparison	Critical Care Suite with Pneumothorax Detection AI Algorithm	BoneView (K212365)
Device Classification	Radiological computer assisted detection and diagnosis software Class II, QBS	Radiological computer assisted detection and diagnosis software Class II, QBS
Targeted clinical condition, anatomy, and imaging modality	Pneumothorax Chest/Lung AP/PA Chest X-Ray Imaging	Fracture Ankle, Foot, Knee, Femur, Wrist, Hand, Elbow, Forearm, Humerus, Shoulder, Clavicle, Pelvis, Hip, Ribs, Thoracic Spine, Lumbar Spine 2D Radiographic Images
Algorithm Inferencing Mechanism	AI deep learning algorithms designed to detect pneumothorax in frontal chest X-ray images to aide in identifying and highlighting pneumothoraxes during the review of radiographs.	AI supervised deep learning algorithm designed to aide in identifying and highlighting fractures during the review of radiographs.
Computational Platform	Critical Care Suite is designed as a self-contained software module deployable on various computational and x-ray imaging system platforms	Deployment on-premises or on cloud and connection to several computing platforms and X-ray imaging

Product Device Comparison	Critical Care Suite with Pneumothorax Detection AI Algorithm	BoneView (K212365)
	such as Digital Projection Radiographic Systems, PACS, On Premise or On Cloud.	platforms such as X-ray radiographic systems, or PACS
Algorithm Outputs	1. Configurable DICOM tag that identifies if a suspected pneumothorax was detected. 2. Image annotations that contain: • Flag if a suspected pneumothorax was detected • Graphical representation of the algorithms confidence in the algorithms result • Overlay (color or grayscale) that localizes the pneumothorax within the image	1. Optional Summary Table with the results of the overall study 2. Results Image that contains • Region of Interest that is a solid or dotted rectangle based on confidence of the algorithm • Summary including the number of regions of interest that are displayed and a caution message if it was identified that the image was not part of the indications for use of BoneView.
Destination for Viewing Algorithm Results	Image annotation on a secondary DICOM image and a DICOM message that identifies if a suspected pneumothorax was detected within the study. The output can be immediately used to visualize the results on any DICOM destination such as a user's images storage system (PACS) or the x-ray system.	Image annotations made on copy of original image or image annotations toggled on/off. The output can be immediately used to visualize the result on any DICOM destination such as a user's images storage system (PACS) or other radiological equipment (X-Ray System)

Clinical and Non-Clinical Tests:	Summary of Non-Clinical Tests: The following quality assurance measures were applied to the development of Critical Care Suite with Pneumothorax Detection AI Algorithm and deployment onto the AMX Navigate system: 1. Risk Analysis 2. Requirements Reviews 3. Design Reviews 4. Testing on unit level (Module verification) 5. Integration testing (System verification) 6. Performance testing (Verification) 7. Safety testing (Verification) 8. Simulated use testing (Validation) Critical Care Suite with Pneumothorax Detection AI Algorithm specific verification was conducted to demonstrate proper implementation of Critical Care Suite software design requirements.

	Regression testing on the AMX Navigate feature functionality was conducted to verify proper integration of Critical Care Suite with Pneumothorax Detection AI Algorithm into the AMX Navigate software and device. Validation was performed on AMX Navigate with integrated Critical Care Suite with Pneumothorax Detection AI Algorithm. Design verification and validation testing was performed to confirm that the safety and effectiveness of the device has not been affected. The test plans and results have been executed with acceptable results. <u>Summary of Clinical Tests:</u> The Pneumothorax Detection AI Algorithm was developed using over 12,000 images from six sources, including the National Institute of Health and sites within the United States, Canada, and India. This data was then segregated into training, verification, and validation datasets. The final validation ground truth dataset included 804 images from two North American sites that were not used in the training process of the algorithm. A mix of cases with low, moderate, and high complexity were included in the dataset. 544 images were acquired on GE HealthCare scanners and 264 images acquired on non-GE Healthcare scanners. Only one site was able to provide age and gender demographics which included a distribution of 51.2% males and 48.8% females, with a median age of 68 (min 18, max 90+). The reference standard was established by three blinded radiologists. The standalone performance of the Pneumothorax Detection AI Algorithm was tested against this dataset establishing that the algorithm can detect a pneumothorax within a frontal chest x-ray image and that the Pneumothorax Overlay can localize a suspected pneumothorax. The ground truth dataset adequately analyzed all the primary and secondary endpoints and the results met the defined passing criteria. The Pneumothorax Detection AI Algorithm achieved an AUC of 96.1% (94.9%, 97.2%), a sensitivity of 84.3% (80.6%, 88.0%) and a specificity of 93.2% (90.8%, 95.6%) for detection of pneumothoraxes on both anteroposterior and posteroanterior frontal chest x-ray images. The algorithm also had high sensitivity for detecting large pneumothoraxes with a sensitivity of 96.3% (93.1%, 99.2%) and small pneumothorax with a sensitivity of 75.0% (69.2%, 80.8%). Additionally, the Pneumothorax Overlay was assessed on the true positive cases identified above, and it partially localized 98.1% (96.6%, 99.6%) of the actual pneumothorax within an image between the apical, lateral, and inferior regions of a lung. It performed with full agreement between these regions 67.8% (62.7%, 73.0%). It also performed with a DICE Similarity Coefficient of 0.705 (0.683, 0.724) indicating that on average 70.5% of the Pneumothorax Overlay area and the true area of a pneumothorax within an image overlap. A multi-reader multi-case study was conducted to assess that the use of the Critical Care Suite with Pneumothorax Detection AI Algorithm improves reader performance within the intended use population in detecting / diagnosing a pneumothorax in a frontal chest x-ray image. This study consisted of 10 independent readers to adequately analyze all the primary and secondary endpoints of varied experiences levels representing the

	clinical users who would interact with the Critical Care Suite with Pneumothorax Detection AI Algorithm: radiologists (Rad.), internal medicine (IM) physicians, emergency medicine (ER) physicians, and nurse practitioners. This study contained 400 images from the original validation ground truth dataset used to determine the standalone performance of the algorithm, and adequately analyzed that all the primary and secondary endpoints met the defined passing criteria. Critical Care Suite with Pneumothorax Detection AI Algorithm improved reader performance for detection of pneumothorax, measured by mean AUC, by 14.5% (7.0%,22.0%; p=.002), from 76.8% non-aided to 91.3% aided. Reader sensitivity increased by 16.3% (13.1%, 19.5%; p<.001) from 67.4% non-aided to 83.7% aided. Reader specificity increased by 12.4% (9.6%, 15.1%; p<.001) from 76.6% non-aided to 89.0% aided. The overall performance by size was also improved. The readers showed an improvement for detection of large pneumothorax measured by mean AUC 10.5% (3.2%, 17.8%, p=0.009) and sensitivity 13.4% (10.0%, 16.9%, p<.001). The readers showed an improvement for detection of small pneumothorax measured by mean AUC 17.6% (9.3%, 25.9%, p<0.001) and sensitivity 18.7% (13.8%, 23.6%, p<.001). The different clinical user's improvements in mean AUC were assessed, and it was noted that all physicians (Rad, IM, ER) improved 10.4% (2.8%, 17.9%, p=0.015), nurse practitioners improved 24.1% (1.2%, 47.0%, p=0.045), radiologists improved 2.4% (-1.0%, 5.7%, p=0.095), and non-radiologists (ER, IM, NP) improved 17.5% (9.6%, 25.4%, p<0.001).
Determination of Substantial Equivalence:	The introduction of Critical Care Suite with Pneumothorax Detection AI Algorithm does not result in any new potential safety risks and uses the same fundamental deep learning based technology to detect pathological finding on 2D X-ray images. Technological differences were assessed through bench testing and clinical validation. Like its predicate the device has been shown to improve intended user accuracy at detecting the targeted pathological finding by licensed healthcare professionals, thus demonstrating that the proposed device is substantially equivalent to its predicate. After analyzing design verification and validation testing on the bench and the clinical testing results it is the conclusion of GE HealthCare that the Critical Care Suite with Pneumothorax Detection AI Algorithm software to be as safe, as effective, and performance is substantially equivalent to the predicate device.