October 29, 2021

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

Re: K211161
Trade/Device Name: Critical Care Suite with Endotracheal Tube Positioning AI Algorithm
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 27, 2021
Received: September 28, 2021

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 and Part 809); 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211161

Device Name

Critical Care Suite with Endotracheal Tube Positioning AI Algorithm

Indications for Use *(Describe)*

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.

Critical Care Suite with the Endotracheal Tube Positioning AI algorithm produces an on-screen image overlay that detects and localizes an endotracheal tube, locates the endotracheal tube tip, locates the carina, and automatically calculates the vertical distance between the endotracheal tube tip and carina. This information is also transmitted to the radiologist for review.

Intended users include licensed qualified healthcare professionals (HCPs) trained to independently place and/or assess endotracheal tube placement and radiologists.

Critical Care Suite with the Endotracheal Tube Positioning AI Algorithm 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 healthcare professional. Critical Care Suite with the Endotracheal Tube Positioning AI Algorithm is indicated for adult-sized 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

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

Date:	September 27, 2021
Submitter:	GE Healthcare, (GE Medical Systems, LLC) 3000 N. Grandview Blvd Waukesha, WI 53188 USA
Primary Contact Person:	Chris Paulik Regulatory Affairs Program Manager GE Healthcare 262-894-5415 Christopher.A.Paulik@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 with Endotracheal Tube Positioning AI Algorithm
Common / Usual Name:	Automated Radiological Image Processing Software
Classification Names and Product Code:	Regulation Name: Medical Image Management and Processing System Regulation: 21 CFR 892.2050 Classification: Class II Product Codes: QIH
Predicate Device:	QLAB Advanced Quantification Software (K191647) Regulation Name: Picture archiving and communications system Regulation: 21 CFR 892.2050 Classification: Class II

	Product Codes: QIH
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 with Endotracheal Tube Positioning AI Algorithm is an additional AI Algorithm incorporated into the Critical Care Suite software previously cleared under K183182. It introduces the Endotracheal Tube Positioning AI Algorithm which is a quantification tool that analyzes frontal chest x-ray images and based on the data in the image determines the location of the tip of an intubated patient's endotracheal tube, determines the location of the carina, and then calculates and displays the vertical distance between them. The distance provided is within the x-ray detector imaging plane and does not take into account the geometric magnification resultant from the geometry of the x-ray acquisition based on source to image distance (SID), patient size, or any impacts due to patient rotation or tube rotation. This information can aide clinical care teams and radiologists to determine the proper placement of the endotracheal tube in an intubated patient. All algorithms previously cleared under K183182 are still available with Critical Care Suite, including the Pneumothorax Detection Algorithm for triage and notification. The benefit of the proposed modification is not specific to the platform on which it is deployed. This benefit applies to all previously cleared computational platforms for Critical Care Suite, including PACS, On Premise, On Cloud and Digital Projection Radiographic Systems. The Optima XR240amx was chosen as the initial platform for deployment because endotracheal tube placement images are almost exclusively acquired on mobile X-ray systems due to the immobilization of the patients being intubated with an endotracheal tube.
Intended Use:	Critical Care Suite with Endotracheal Tube Positioning AI Algorithm is intended to provide automated radiological image processing and analysis tools implementing artificial intelligence including nonadaptive machine learning algorithms trained with clinical and/or artificial data.
Indications for Use:	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. Critical Care Suite with the Endotracheal Tube Positioning AI algorithm produces an on-screen image overlay that detects and localizes an endotracheal tube, locates the endotracheal tube tip, locates the carina, and automatically calculates the vertical distance between the endotracheal tube tip and carina. This information is also transmitted to the radiologist for review.

	Intended users include licensed qualified healthcare professionals (HCPs) trained to independently place and/or assess endotracheal tube placement and radiologists. Critical Care Suite with Endotracheal Tube Positioning AI Algorithm 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 healthcare professional. Critical Care Suite with the Endotracheal Tube Positioning AI Algorithm is indicated for adult-size patients.
Technology:	Critical Care Suite with Endotracheal Tube Positioning AI Algorithm employs the same fundamental scientific technology as its predicate device. It is a deep learning locked AI algorithm that can be deployed on several computing platforms such as PACS, On Premise, On Cloud or Imaging Systems. The patient and user populations are identical to what is provided with Critical Care Suite, adult-sized patients. The Endotracheal Tube Positioning AI Algorithm is an automated radiological image processing and analysis tool, which is equivalent to the image analysis and quantification algorithms provided in the QLAB Advanced Quantification Software. The differences between Critical Care Suite with Endotracheal Tube Positioning AI Algorithm and QLAB Advanced Quantification Software are the acquisition systems that provide the images as well as the specific anatomies that are being analyzed. Critical Care Suite with Endotracheal Tube Positioning AI Algorithm analyzes chest radiographic images where QLAB Advanced Quantification Software analyzes ultrasound images of the heart. This difference does not impact the safety or efficacy of Critical Care Suite with Endotracheal Tube Positioning AI Algorithm since both devices analyze images using deep learning AI technology to identify/visualize anatomical structure and then provide quantification measurements based on that data to aide qualified healthcare professionals trained on endotracheal tube placement and radiologists.

Product Device Comparison	Critical Care Suite with Endotracheal Tube Positioning AI Algorithm	QLAB Advanced Quantification Software (K191647)
Device Classification	Picture archiving and communications system Class II, QIH	Picture archiving and communications system Class II, QIH
Targeted clinical condition, anatomy, and imaging modality	Endotracheal Tube Positioning Visualization and Quantification Chest/Lung Frontal Chest X-Ray Imaging	Right Ventricle Visualization and Quantification Heart Ultrasound Heart Imaging
Algorithm Inferencing Mechanism	AI deep learning algorithms designed to visualize and quantify endotracheal tube positioning in frontal chest X-ray images	AI deep learning algorithm designed to visualize and quantify the right ventricle within heart ultrasound images

Product Device Comparison	Critical Care Suite with Endotracheal Tube Positioning AI Algorithm	QLAB Advanced Quantification Software (K191647)
Computational Platform	On-Device computation (integrated onto x-ray system) Critical Care Suite with Endotracheal Tube Positioning AI Algorithm is designed as a self-contained software module deployable on various computational and imaging system platforms.	Provided as stand-alone product that can function on a standard PC, a dedicated workstation, and on-board Philips' ultrasound systems.
Notification / Visualization Recipient and Timing	qualified healthcare professionals trained on endotracheal tube placement – immediately on device upon image acquisition for Endotracheal Tube Positioning AI Algorithm Radiologist – immediately after images are sent to PACS via secondary capture image and DICOM tag	Clinical Care Team – immediately upon image acquisition on device Radiologist – immediately after images are sent to PACS
Algorithm Outputs	<u>Visualization</u> • Endotracheal tube • Endotracheal Tube Tip • Carina <u>Quantification</u> • Vertical distance between endotracheal tube tip and carina	<u>Visualization</u> • 3D surface modeling of anatomical landmarks of right ventricle <u>Quantification</u> • Numerous distance and volumetric measurements concerning the right ventricle

Clinical and Non-Clinical Tests:	<u>Summary of Non-Clinical Tests:</u> The following quality assurance measures were applied to the development of Critical Care Suite with Endotracheal Tube Positioning AI Algorithm and deployment onto the Optima XR240amx 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 Endotracheal Tube Positioning AI Algorithm specific verification was conducted to demonstrate proper implementation of Critical Care Suite software design requirements. Regression testing on the Optima XR240amx feature functionality was conducted to verify proper integration of Critical Care Suite with Endotracheal Tube Positioning AI Algorithm into the Optima XR240amx software and device. Validation was performed on Optima XR240amx with integrated Critical Care Suite with Endotracheal Tube Positioning 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 performance of the Endotracheal Tube Positioning AI Algorithm was tested against a ground truth dataset. The ground truth dataset contained a sufficient number of images to adequately analyze all the primary and secondary endpoints and the results met the defined passing criteria. The Endotracheal Tube Positioning AI Algorithm achieved an AUC of 0.9999 (0.9998, 1.0000), a sensitivity of 0.9941 (0.9859, 1.0000) and a specificity of 1.0000 (1.0000, 1.0000) for ETT detection. Additionally, the Endotracheal Tube Positioning AI Algorithm achieved an ETT tip to Carina distance measurement success rate of 0.9851 (0.9722, 0.9981), a carina localization success rate 0.9851 (0.9722, 0.9981), an ETT tip localization success rate of 0.9524 (0.9296, 0.9752) and an ETT localization success rate (DICE) of 0.9881 (0.9765, 0.9997).
Determination of Substantial Equivalence:	The introduction of Critical Care Suite with Endotracheal Tube Positioning AI Algorithm does not result in any new potential safety risks, and has the same technological characteristics, and performs as well as the predicate devices currently on the market. After analyzing design verification and validation testing on the bench it is the conclusion of GE Healthcare that the Critical Care Suite with Endotracheal Tube Positioning AI Algorithm software to be as safe, as effective, and performance is substantially equivalent to the predicate device.