Ge Medical Systems, LLC
Chris Paulik
Sr. Regulatory Affairs Manager
3000 N. Grandview Blvd.
Waukesha, WI 53188

April 14, 2026

Re: K253502
Trade/Device Name: Critical Care Suite with Enteric 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: October 30, 2025
Received: October 30, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253502

Please provide the device trade name(s).

Critical Care Suite with Enteric Tube Positioning AI Algorithm

Please provide your Indications for Use below.

Critical Care Suite with Enteric Tube AI Algorithm analyzes frontal chest and abdominal x-ray images and produces an on-screen image overlay that detects and localizes an enteric tube that has been inserted nasally or orally, locates the tube tip, and locates the tube side port (if present). It also produces an on-screen image overlay that detects and localizes the diaphragm and the airways (carina with left and right bronchi). This information is also transmitted to the radiologist for review.

Intended users include licensed qualified healthcare professional (HCP) who have been trained to independently place and/or assess the placement of enteric tubes inserted nasally or orally and radiologists.

Critical Care Suite with the Enteric 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 Enteric Tube Positioning AI algorithm is indicated for both adult and pediatric patients.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K253502

510(k) Summary:

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

Date:	April 13, 2026
Owner / 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@gehelathcare.com
Secondary Contact Person:	Gregory Pessato Regulatory Affairs Director GE Healthcare +33 (6) 34423240 GregoryPessato@gehealthcare.com
Device Trade Name:	Critical Care Suite with Enteric Tube Positioning AI Algorithm
Common / Usual Name:	Medical Image Management and Processing System
Regulation Name:	Medical Image Management and Processing System
Regulation:	21 CFR 892.2050
Classification:	Class II
Product Code:	QIH
Predicate Device:	Critical Care Suite with Endotracheal Tube Positioning AI Algorithm (K211161) Regulation Name: Medical Image Management and Processing System Regulation: 21 CFR 892.2050 Classification: Class II Product Codes: QIH
Device Description:	Critical Care Suite is a suite of AI algorithms for the automated image analysis of x-rays acquired on a digital x-ray system for the presence of critical findings, quality checks and/or measurements. Critical Care Suite with Enteric Tube Positioning AI Algorithm is a quantification tool that analyses chest and abdominal x-ray images for the presence of an enteric tube that has been inserted either nasally or orally. This algorithm was developed using over 12,000 images from 15 sources located across the United States, Canada, European Union, and India. If an enteric tube is detected, it highlights the tube's location within the image and locates its tip and side port (if present). It then highlights the airways (carina with the left and right bronchi) as well as the diaphragm.

	The users of this algorithm are those licensed qualified healthcare providers (HCP) that have been trained to independently place and/or assess the placement of an enteric tube and radiologists. The outputs of the proposed algorithm are intended to assist these users in their assessment of the enteric tube placement within pediatric and adult patients. Critical Care Suite with Enteric Tube Positioning AI Algorithm is a software module that can be deployed on several computing platforms such as PACS, On Premise, On Cloud or Digital Projection Radiographic Systems. The AMX Navigate mobile x-ray system was chosen as the initial platform for deployment because enteric tube placement images are almost exclusively acquired on mobile x-ray systems due to the limited mobility of the patients requiring an enteric tube.
Intended Use:	Critical Care Suite with Enteric 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 with Enteric Tube AI Algorithm analyzes frontal chest and abdominal x-ray images and produces an on-screen image overlay that detects and localizes an enteric tube that has been inserted nasally or orally, locates the tube tip, and locates the tube side port (if present). It also produces an on-screen image overlay that detects and localizes the diaphragm and the airways (carina with left and right bronchi). This information is also transmitted to the radiologist for review. Intended users include licensed qualified healthcare professional (HCP) who have been trained to independently place and/or assess the placement of enteric tubes inserted nasally or orally and radiologists. Critical Care Suite with the Enteric 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 Enteric Tube Positioning AI algorithm is indicated for both adult and pediatric patients.

Product Device Comparison	**Critical Care Suite with Enteric Tube AI Algorithm**	**Critical Care Suite with Endotracheal Tube Positioning AI Algorithm (K211161)**
Device Classification	Automated Radiological Image Processing Software Class II, QIH	Automated Radiological Image Processing Software Class II, QIH
Targeted clinical condition, anatomy, and imaging modality	Enteric Tube Placement Chest/Lung and Stomach Frontal Chest and Abdominal X-Ray Imaging	Endotracheal Tube Placement Chest/Lung Frontal Chest X-Ray Imaging

Product Device Comparison	Critical Care Suite with Enteric Tube AI Algorithm	Critical Care Suite with Endotracheal Tube Positioning AI Algorithm (K211161)
Algorithm Inferencing Mechanism	AI deep learning algorithms designed to visualize and quantify enteric tube positioning in frontal chest and abdominal x-ray images	AI deep learning algorithms designed to visualize and quantify endotracheal tube positioning in frontal chest x-ray images
Computational Platform	On-Device computation (integrated onto x-ray system) Critical Care Suite with Enteric Tube Positioning AI Algorithm is designed as a self-contained software module deployable on various computational and imaging system platforms.	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.
Notification / Visualization Recipient and Timing	Clinical Care Team – Licensed qualified healthcare professionals trained on enteric tube placement – immediately on device upon image acquisition for Enteric Tube Positioning AI Algorithm Radiologist – immediately after images are sent to PACS via secondary capture image and DICOM tag	Clinical Care Team – Licensed 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
Algorithm Outputs	Visualization • Enteric tube • Enteric Tube Tip • Enteric Tube Side Port • Diaphragm • Airways (carina with left and right bronchi). Quantification • None	Visualization • Endotracheal tube • Endotracheal Tube Tip • Carina Quantification • Vertical distance between the endotracheal tube tip and carina
Destination for Viewing Algorithm Results	Image annotation on a secondary DICOM image and a DICOM tag that identifies if an enteric tube 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 annotation on a secondary DICOM image and a DICOM tag that identifies if an endotracheal tube was detected within the study which includes the vertical distance measurement between the endotracheal tube tip and carina. 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.

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 Enteric Tube Positioning 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 Enteric Tube Positioning AI Algorithm specific verification was conducted to demonstrate proper implementation of Critical Care Suite software design requirements. Regression testing on the AMX Navigate functionality was conducted to verify proper integration of Critical Care Suite with Enteric Tube Positioning AI Algorithm into the AMX Navigate software and device. Validation was performed on AMX Navigate with integrated Critical Care Suite with Enteric 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. Summary of Clinical Tests: The performance of the Enteric Tube Positioning AI Algorithm was tested against a ground truth dataset. The ground truth dataset contained 954 images that were not used in the development of the algorithm from five sites across North America and the United Kingdom to adequately analyze all the primary and secondary endpoints and the results met the defined passing criteria. This dataset included images from both male and female patients that ranged in age from neonates to over 65 years of age. It included both chest and abdominal x-ray images (including babygrams) of varying image quality and difficulty, such as other objects within the image (e.g. breathing tubes). It also included multiple enteric tube types that did or did not include a radiopaque line as well as images acquired on systems from at least eight different venders. The ground truth was determined by five expert annotators that included both board certified general and pediatric radiologists that conducted two reads on each image with an arbitration process.

	The Enteric Tube Positioning AI Algorithm achieved a sensitivity of 0.992 (0.982, 0.997) and a specificity of 0.975 (0.947, 0.991). It also displayed strong localization capabilities with a mean DICE score of 0.911 (0.912, 0.921) for tube localization. For tube tip detection, the algorithm achieved a sensitivity of 0.957 (0.935, 0.973) and a specificity of 0.941 (0.901, 0.968). In assessing side ports, it reached a sensitivity of 0.931 (0.904, 0.952) and a specificity of 0.859 (0.801, 0.905). Additionally, the algorithm delivered mean DICE scores of 0.741 (0.730, 0.753) for airway localization and 0.821 (0.808, 0.834) for diaphragm localization. It also provided precise localization with mean errors of 1.789 mm (1.222, 2.356) for the tube tip and 2.575 mm (1.731, 3.420) for the side port.
Determination of Substantial Equivalence:	The introduction of Critical Care Suite with Enteric 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 device. After analyzing design verification and validation testing on the bench and in the clinical ground truth study it is the conclusion of GE HealthCare that the Critical Care Suite with Enteric Tube Positioning AI Algorithm software to be as safe, as effective, and performance is substantially equivalent to the predicate device.