June 24, 2026

Ge Medical Systems, LLC
℅ Veronica Aguayo
Regulatory Affairs Leader
3000 N. Grandview Blvd.
WAUKESHA, WISCONSIN 53188

Re: K253560
Trade/Device Name: Enhanced Boundary for PCCT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: May 22, 2026
Received: May 22, 2026

Dear Veronica Aguayo:

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,

FDA Digitally signed by GABRIELA M. RODAL -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253560

Device Name
Enhanced Boundary for PCCT

Indications for Use *(Describe)*
Enhanced Boundary for PCCT is a deep learning-based CT processing method used for improved soft tissue delineation in routine head exams with and without contrast. Enhanced Boundary for PCCT may be used for patients of all ages.

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 OF SAFETY AND EFFECTIVNESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h):

Date: November 14, 2025

Submitter:
GE Medical Systems, LLC
3000 N. Grandview Blvd.
Waukesha, Wisconsin 53188

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Device Trade Name: Enhanced Boundary for PCCT
Device Classification Class II
Regulation Number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK

Predicate Device Information

Device Name: Revolution Apex
Manufacturer: GE Medical Systems, LLC
510(k) Number: K213715
Regulation Number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

Routine brain imaging is one of the most challenging CT applications due to the low contrast between gray and white matter, which typically results in viewing images with a narrow window width. When images are viewed in a narrow window width, the noise variations and artifacts in the image become more obvious. Since routine brain scanning is a frequent use case for CT, and it is a challenging application, there is a desire to develop specific applications aimed at further improving the visualization between gray and white matter in the brain.

Enhanced Boundary for Photon Counting CT (PCCT) is an optional, user selectable, deep learning-based processing algorithm trained to enhance soft tissue boundaries in routine head exams obtained using Photonova Spectra systems. Enhanced Boundary for PCCT has three strengths that the user can choose depending on enhancement preferences. This feature aims to enhance CT images of the brain, specifically at the borders of three main brain components – gray matter, white matter, and cerebrospinal fluid (CSF). The benefits provided by this enhancement include improved boundary delineation (reduced blurring at the brain tissue boundaries) and improved CT number stability.

Intended Use

Enhanced Boundary for PCCT is a deep learning-based CT processing method intended for head imaging.

Indications for Use

Enhanced Boundary for PCCT is a deep learning-based CT processing method used for improved soft tissue delineation in routine head exams with and without contrast. Enhanced Boundary for PCCT may be used for patients of all ages.

Technological Characteristics

Since the Enhanced Boundary for PCCT option is deployed within Photonova Spectra acquisition and processing software, it utilizes the same hardware and software platform to process images. The table below summarizes the substantive feature/technological differences between the predicate device, host system, and the proposed device. The changes described below do not change the fundamental technology of the predicate device or host system and do not raise any new questions of safety and effectiveness.

Specification	**Predicate Device** **Revolution Apex** **(K213715)**	**Host System** **Photonova Spectra** **(K253520)**	**Proposed Device** **Enhanced Boundary for PCCT** (on Photonova Spectra)
Patient Population	Patients of all ages	Patients of all ages	Patients of all ages
Supported kVps	70, 80, 100, 120, 140 kVp	120 kVp only	120 kVp only
Reconstruction Matrix Available for Routine Neuro Soft Tissue	512 x 512	512 x 512	512 x 512
Hardware	Revolution Apex System including CT Gantry, Patient Table, Acquisition, and operator console computer.	Photonova Spectra System including CT Gantry, Patient Table, Acquisition, and operator console computer.	Enhanced Boundary for PCCT is a software only option implemented into the operator console computer for host system Photonova Spectra.
Image Reconstruction Algorithms	FBP ASiR-V DLIR GSI-DLIR	FBP with True Fidelity DL for PCCT	Enhanced Boundary for PCCT is a CT processing algorithm incorporated into the Photonova Spectra image reconstruction process.
Clinical Workflow	The Revolution Apex User Interface allows for modifications of image reconstruction settings based on users desired image display and workflow set up.	The Photonova Spectra User Interface allows for modifications of image reconstruction settings based on users desired image display and workflow set up.	When the Enhanced Boundary for PCCT option is enabled, it integrates into the same workflow and User Interface as the host system Photonova Spectra.
Neuro CT Enhancement Algorithms	Enhanced Boundary (EB1-3) Enhanced Contrast (EC1-3)	No algorithms specifically for neuro CT enhancement.	Enhanced Boundary for PCCT (EB1-3)

Determination of Substantial Equivalence

Enhanced Boundary for PCCT has successfully completed the design control testing per GE HealthCare's quality system. No additional hazards were identified, and no unexpected test results were observed. Enhanced Boundary for PCCT was designed under GE HealthCare's QMS per the Quality System Regulations of 21CFR 820 and ISO 13485. GEHC believes that the successfully completed design verification & validation, as well as the extensive bench testing is sufficient for FDA's substantial equivalence determination.

The following quality assurance measures have been applied to the development of the system:

- Requirement Definition
- Risk Analysis and Control
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
    - Code Review
    - Software Unit Implementation
    - Software Integrations and Integration Testing
- System Testing
    - Safety Testing (Verification)
    - Image Performance Testing (Verification)
    - Simulating Use Testing (Validation)
- Software Release

The testing and results did not raise different questions of safety and effectiveness than associated with predicate device.

Summary of Non-Clinical Testing

A range of bench testing on phantoms and clinical images were performed to measure the performance of Enhanced Boundary for PCCT. The tests include well established industry-standard IQ metrics and claims substantiation tests to demonstrate overall image quality and support substantial equivalence of the algorithm on the Photonova Spectra scanner's traditional metrics.

The result of the bench testing showed that Enhanced Boundary for PCCT can reduce blurring between gray matter, white matter, and cerebrospinal fluid without significantly changing their CT number and the algorithm does not significantly increase the image noise, in comparison with a sharper reconstruction kernel.

Summary of Clinical Testing

The clinical testing was carried out in the form of a reader study of sample clinical data processed using Enhanced Boundary for PCCT software. The images were evaluated by US board-certified radiologists.

Additionally, clinical testing included reader assessment of hallucination risks across a range of challenging head CT cases, with results demonstrating that Enhanced Boundary for PCCT preserves anatomical correctness and diagnostic interpretability even under challenging clinical conditions. There were no findings of hallucinations.

The result of this reader study validated that Enhanced Boundary for PCCT provides diagnostic value by improving delineation of the boundaries in routine head exams with and without contrast and improves confidence in the assessment of soft tissue structures in the brain.

Substantial Equivalence

Enhanced Boundary for PCCT was developed under GEHC's quality system. Design verification, along with bench testing and the clinical reader study provided in this submission demonstrates that Enhanced Boundary for PCCT is substantially equivalent and hence as safe and as effective as the predicate and host devices. GEHC's quality system's design, verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the host system. GE HealthCare believes that Enhanced Boundary for PCCT is substantially equivalent to the predicate and host devices and hence is safe and effective for its intended use.