March 20, 2026

GE Medical Systems, LLC
% Laura Turner
Regulatory Affairs Manager
3000 N. Grandview Blvd.
WAUKESHA, WI 53188

Re: K253520
Trade/Device Name: Photonova Spectra, Photonova Spectra Select
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 19, 2026
Received: February 19, 2026

Dear Laura Turner:

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,

Lu Jiang

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)*
K253520

Device Name
Photonova Spectra, Photonova Spectra Select

Indications for Use *(Describe)*
The Photonova Spectra, Photonova Spectra Select system is a silicon-based spectral photon counting detector X-ray Computed Tomography scanner.

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles.

The system acquires multi-energy data in every scan and natively generates high resolution monochromatic images and material density maps to facilitate visualizing and analyzing information about anatomical and pathological structures.

The system is indicated for head, whole body, cardiac, and vascular CT applications. The system is indicated for patients of all ages. The images can be post-processed to produce additional imaging planes or analysis results.

The system is indicated for lung cancer screening for patients meeting the established inclusion criteria of programs/protocols that have been published by either a governmental body or professional medical society.*

* Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011;365:395-409) and subsequent literature, for further information.

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

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 12, 2025
Submitter:	GE Medical Systems, LLC 3000 N. Grandview Blvd. Waukesha, Wisconsin 53188
Primary Contact:	Laura Turner Regulatory Affairs Manager Phone: 1 (262) 200-1044 Email: Laura.Turner@gehealthcare.com
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Device Trade Name:	Photonova Spectra, Photonova Spectra Select
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, Cleared on December 17, 2021
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Reference Device Information

Device Name:	Deep Learning Image Reconstruction for Gemstone Spectral Imaging (DLIR-GSI)
Manufacturer:	GE Medical Systems, LLC

510(k) Number:	K201745
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK
Device Name:	Deep Learning Image Reconstruction (DLIR) (TrueFidelity)
Manufacturer:	GE Medical Systems, LLC
510(k) Number:	K213999
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

Photonova Spectra is the next iteration of the predicate, the Revolution Apex platform (K213715), introducing a new Deep Silicon (dSi) photon counting detector for CT imaging. Photonova Spectra aims to realize an improvement in both spatial resolution and spectral imaging performance relative to traditional Energy Integrating Detector (EID) systems for diagnostic CT. With photon-counting detectors that can better discriminate energies, spectral CT imaging can natively provide valuable information about tissue composition and material density without the need for active filtration or kVp modulation by performing material decomposition directly from native multi-energy data.

The Photonova Spectra system is an ultra-premium multi-slice CT scanning system comprised of a gantry, a detector, an x-ray tube, a power distribution unit (PDU), a table, a system cabinet, a scanner desktop computer and user interface, and associated accessories. It is designed as a volumetric CT scanner to provide advanced imaging capability for a range of clinical applications.

Compared to the predicate Revolution Apex, the key differences of the Photonova Spectra System consist of a Deep Silicon (dSi) X-ray detector capable of directly converting X-ray photons to electrical signals, advanced detector data acquisition hardware for managing and processing of large volumes of data, advanced computer hardware and an enhanced image chain for generating High Definition (HD) Spectral and Ultra High Definition (UHD) image series.

The Photonova Spectra image chain is developed to calibrate, pre-process, reconstruct, and post-process images for use in medical imaging applications. Customized for photon counting detection physics and capability, Photonova Spectra does not require user to choose between single kV and dual energy acquisition modes. With Photonova Spectra, all acquisitions are spectral with 8 energy bins over the full high-resolution detector, and the data is stored real-time on the rotating side as the acquisition completes over the full scan sequence.

The system will be offered with either an 80 mm dSi detector and 40 mm dSi detector model configurations, commercialized as Photonova Spectra and Photonova Spectra Select, respectively. The detector size is the key differentiator, but all core technology and functionality are identical.

Intended Use

The system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications.

Indications for Use

The Photonova Spectra, Photonova Spectra Select system is a Silicon-based Spectral Photon Counting Detector X-ray Computed Tomography Scanner.

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles.

The system acquires multi-energy data in every scan and natively generates high resolution monochromatic images and material density maps to facilitate visualizing and analyzing information about anatomical and pathological structures.

The system is indicated for head, whole body, cardiac, and vascular CT applications. The system is indicated for patients of all ages. The generated images can be post-processed to produce additional imaging planes or analysis results.

The system is indicated for lung cancer screening for patients meeting the established inclusion criteria of programs/protocols that have been published by either a governmental body or professional medical society. *

* Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011;365:395-409) and subsequent literature, for further information.

Technological Characteristics

Photonova Spectra has identical intended use to the predicate, Revolution Apex, and did not alter use environment, or patient population. While Photonova Spectra shares several primary hardware components with the predicate, the proposed device introduces a new photon counting detector utilizing a silicon semiconductor material and an enhancement to the Quantix X-ray tube control software to produce an additional extra small focal spot to pair with the high-resolution detector geometry. Photonova Spectra also includes a next generation deep learning reconstruction commercially known as TrueFidelity DL for PCCT using a multi-layer convolution neural network (CNN) that is designed to produce low noise images. The proposed TrueFidelity DL for PCCT is intended for routine clinical use and based on the same framework and training methodology as the reference devices (DLIR and DLIR-GSI) that are utilized by the Revolution Apex. The proposed TrueFidelity DL for PCCT is implemented as the system's default native reconstruction with an inherent baseline level of denoising, while also offering user-selectable parameters (Low, Medium, High) to modulate denoising strength according to user preference.

Specification	Predicate Device Revolution Apex (K213715)	Proposed Device Photonova Spectra
Contraindications	None	Same
Patient Population	Patients of all ages	Same
Gantry	• 80 cm patient bore • Rotation Speeds: 0.23, 0.28, 0.35, 0.5, 0.6, 0.7, 0.8, 0.9, and 1.0 seconds per rotation	• 80 cm patient bore • Rotation Speeds: 0.23, 0.28, 0.35, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0 & **2.0** seconds per rotation
Detector	• Up to 160 mm in Z-direction with up to 50cm Scan field of view	• **Up to 80 mm** in Z-direction with up to 50 cm scan field of view

Specification	Predicate Device Revolution Apex (K213715)	Proposed Device Photonova Spectra
	• 256 rows, 0.625 mm pixel pitch • Energy Integrating • Gemstone Scintillator Material • Detector Thermal System (DTS) with high RPM fans	**(40 mm option)** • **192 rows, 0.2 mm pixel pitch in XY and 0.4 mm pixel pitch in Z** • **Photon Counting with 8 discrete energy bins** • **Silicon Semiconductor Material** • Detector Thermal System (DTS) with higher RPM fans
X-Ray Tube	Quantix X-Ray Tube • 70, 80, 100, 120, 140 kVp • Focal Spot sizes: Extra Large, Large, Small	Quantix X-Ray Tube • **120 kVp** • Focal Spot sizes: Extra Large, Large, Small, **Extra Small**
Collimator	Wolverine 2 Collimator • Diagnostic Bowties: Small, Medium, Large • Scout: SmartScout Filter • Calibration: No dedicated filter.	**Badger Collimator** • **Diagnostic Bowties: Small, Large** • Scout: SmartScout Filter • **Calibration: Tungsten Filter**
Patient Table	• Tables with scannable range of 2000 mm & 1700mm • Load capacity 675 lbs	Same
Scan Modes	• Scout • Axial • Helical • Cine • Cardiac • Gated • High Definition • Fluoro (axial) • GSI • SmartScout • ECG-Less cardiac (K233750)	• Scout • Axial • Helical • Cardiac • Gated
Image Reconstruction Matrix	512 x 512 1024 x 1024	Same
Reconstruction Algorithms	FBP ASiR-V (K13640) DLIR (K213999) GSI-DLIR (K201745)	FBP with **TrueFidelity DL for PCCT**

Determination of Substantial Equivalence

Photonova Spectra has completed testing and in compliance with AAMI/ANSI ES 60601-1 and IEC60601-1 Ed. 3.2 and its associated collateral and particular standards, 21 CFR Subchapter J, and NEMA standards XR 25, and XR 28. Engineering design verification, validation and bench testing are in support of substantial equivalence between the subject device and predicate device. The following quality assurance measures were 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. We consider the Photonova Spectra is substantially equivalent to the predicate device, Revolution Apex.

Summary of Non-Clinical Testing

Verification and validation testing have been done as required by design control procedures under GE Healthcare's quality system. This includes risk management, software verification and validation testing as well as image quality and dose performance evaluation using well established metrics and methods.

Additionally, substantial equivalence of image quality was demonstrated for the system's DL baseline level of denoising with FBP-based reconstruction. The testing includes evaluation of a comprehensive set of image quality metrics and includes acquisitions at varying dose levels and phantom sizes. This aims to demonstrate equivalency in images by assessing that the CT number, water accuracy, mean CT number over a range of spectral tasks, in-plane resolution, cross-plane resolution and noise texture (as measured by the noise power spectrum) are substantially equivalent.

IQ and dose evaluation include:

- Test using standard IQ, QA, ACR and anthropomorphic pediatric phantoms for standard conditions as well as challenging conditions such as with phantoms simulating large patients.
- Low contrast detectability (LCD) studies were conducted incorporating a model observer approach.
- Elements of performance testing in accordance with IEC 61223-3-5 ed 2.

Summary of Clinical Testing

The clinical testing was carried out in the form of a reader study of sample clinical covering a wide range of clinical scenarios, including Neuro, Body, and Cardiac/Chest. Images were evaluated by US board-certified Radiologists.

Additionally, clinical testing included an evaluation by US board certified Radiologists to compare the various levels of user-prescribed denoising to support the conclusion that the system-offered DL reconstruction preserves diagnostic interpretability and overall performance. Specifically, a comparative clinical evaluation of challenging cases from the above-mentioned reader study demonstrated that the system's DL baseline level of denoising was substantially equivalent to FBP-based reconstruction, with no introduced or removed anatomical information. No reader identified any added, removed, or reduced diagnostic information in any DLIR setting, and all pathologies were consistently visualized across all DL reconstructions.

The result of this reader study validated that Photonova Spectra provides diagnostic utility and is safe and effective for its intended use.

Substantial Equivalence

GE HealthCare believes that Photonova Spectra is safe and effective and performs in a substantially equivalent manner to the unmodified predicate device Revolution Apex (K213715).

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 predicate.