



October 30, 2024

Siemens Medical Solutions USA, Inc.
Joseph Howell
Regulatory Affairs Professional
810 Innovation Drive
Knoxville, Tennessee 37932

Re: K243186

Trade/Device Name: Symbia Pro.specta Q3 (11364751); Symbia Pro.specta X3 (11364752); Symbia Pro.specta X7 (11364753); Symbia Pro.specta VA30A Family

Regulation Number: 21 CFR 892.1200

Regulation Name: Emission Computed Tomography System

Regulatory Class: Class II

Product Code: KPS, JAK

Dated: September 30, 2024

Received: September 30, 2024

Dear Joseph Howell:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent 'FDA' watermark.

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

k243186

Device Name

Symbia Pro.specta Q3 (11364751);
Symbia Pro.specta X3 (11364752);
Symbia Pro.specta X7 (11364753);
Symbia Pro.specta VA30A Family

Indications for Use (Describe)

The Symbia Pro.specta systems are intended for use by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning or additional uses.

SPECT: The SPECT component is intended to detect or image the distribution of radionuclides in the body or organ (physiology), using the following techniques: planar imaging, whole body imaging, and tomographic imaging for isotopes with energies up to 588 keV.

CT: The CT component is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data (anatomy) from either the same axial plane taken at different angles or spiral planes taken at different angles.

SPECT+CT: The SPECT and CT components used together acquire SPECT/CT images. The SPECT images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (SPECT) and anatomical (CT) images.

Software: The SPECTsyngo software is an acquisition, display and analysis package intended to aid the clinician in the assessment and quantification of pathologies in images produced from SPECT, PET, CT, and other imaging modalities.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. 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.

There are no known contraindications.

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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K243186

510(k) Summary

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter: Joseph Howell
Regulatory Affairs Specialist
Siemens Molecular Solutions USA, Inc.
810 Innovation Drive
Knoxville, TN 37932

Manufacturer: Siemens Medical Solutions USA, Inc.
Molecular Imaging
2501 North Barrington Road
Hoffman Estates, IL 60192

Telephone Number: (865) 218 - 2343

Date of Submission: September 30, 2024

Identification of the product

Device Proprietary Name: Symbia Pro.specta Q3, Symbia Pro.specta X3, Symbia Pro.specta X7 (also known as Symbia Pro.specta VA30 Family)

Common Name: Single-Photon Emission Computed Tomography (SPECT) System
Computed Tomography (CT) System

Classification Name: Emission Computed Tomography System per 21 CFR 892.1200
Computed Tomography X-Ray System per 21 CFR 892.1750

Product Code: KPS and JAK

Classification Panel: Radiology

Device Class: Class II

Marketed Devices to which Equivalence is claimed:

Predicate Device:

Device Proprietary Name: Symbia VA20A Family Update

Common Name: Single-Photon Emission Computed Tomography (SPECT) System
Computed Tomography (CT) System

Classification Name: Emission Computed Tomography System per 21 CFR 892.1200
Computed Tomography X-Ray System per 21 CFR 892.1750

Manufacturer: Siemens Medical Solutions USA, Inc.

Product Code: KPS and JAK

Classification Panel: Radiology

Device Class: Class II

510(k) Number: K231102

Reference Device:

Device Name and 510(k) numbers: Scan&GO, SOMATOM Go.Platform

Common Name: Computed Tomography X-Ray System

Classification Name: Computed Tomography X-Ray System per 21 CFR 892.1750
Picture Archiving and Communications System per 21 CFR 892.2050

Manufacturer: Siemens Healthcare GmbH

Product Code: LLZ, JAK

Classification Panel: Radiology

Device Class: Class II
510(k) Number: K233650

Reference Device:

Device Name and 510(k) numbers: MI View&Go VA30A
Common Name: Image Processing Software
Classification Name: Picture Archiving and Communications System per 21 CFR 892.2050
Manufacturer: Siemens Medical Solution, USA, Inc.
Product Code: LLZ
Classification Panel: Radiology
Device Class: Class II
510(k) Number: K242300

Device Description:

The Siemens Symbia Pro.specta VA30A Family consists of Single-Photon Emission Computed Tomography (SPECT) scanner and integrated hybrid x-ray Computed Tomography (CT) and SPECT scanner.

The SPECT subsystem images and measures the distribution of radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and integrates CT's anatomical detail for precise reference of the location of the metabolic activity.

The CT component produces cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.

The system can be used as an integrated SPECT and CT modality while also enabling independent functionality of SPECT and CT as stand-alone diagnostic imaging devices.

Siemens Symbia Pro.specta VA30A Family maintains the same intended use and indications for use as the commercially available Symbia Pro.specta VA20A family (K231102).

Symbia Pro.specta VA30A Family are hybrid modality imaging systems comprised of two separate but integrated components: a gamma camera (SPECT) and a CT. The gamma camera is based on hardware and software features that generate nuclear medicine images based on the uptake of radioisotope tracers in a patient's body. The CT system (spiral CT) is designed to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.

The combination of SPECT and CT in a single device has several benefits. The SPECT subsystem images biochemical function while the CT subsystem images anatomy. The combination enables scans that not only indicate function, e.g., how active a tumor is, but precise localization, e.g., the precise location of that tumor in the body.

In addition, CT can be used to correct for the attenuation in SPECT acquisitions. Attenuation in SPECT is an unwanted side effect of the gamma rays scattering and being absorbed by tissue. This can lead to errors in the final image. The CT directly measures attenuation and can be used to create a 3D attenuation map of the patient which can be used to correct the SPECT images. The SPECT-CT scanner can be used to image and track how much dose was delivered to both the target and the surrounding tissue.

The systems consist of display equipment, data storage devices, patient and equipment supports and component parts and accessories.

Symbia Pro.specta VA30A release is the product name for the addition of features to the approved Symbia Pro.specta VA20A Family (K231102). The Symbia Pro.specta VA30A devices are based on the Symbia Pro.specta VA20A Family. The difference lies in the additional features/changes. The Intended Purpose and fundamental scientific technology remain unchanged.

Proposed new features in Symbia Pro.specta VA30 include:

- Cardiac Quantification
- High Speed Mode
- NM Remote Reconstruction on myExam Satellite

Other changes:

- Scanning improvements
- Recon improvements
- General software improvements
- Miscellaneous improvements

The table below summarizes the differences between the subject and predicate devices.

Features	Symbia Pro.specta VA30 (Subject Device)	Symbia Pro.specta VA20 (Predicate Device K231102)
Intended/Indication For Use	Same	Same
Biocompatibility	Same	Same
Productivity Features	Same	Same
Optional Pallets/Accessories/Collimators	Same	Same
MI View&GO updates	Improvements made to Layout Editor Tool. All changes are included in K242300.	N/A
Operating System	Same	Same
Computer Systems additions	Same	Same
Scan Planning Updates	Same	Same
SPECT Software updates	Cardiac Quantification has been added as an option for all 3 models (Q3, X3, & X7). High Speed mode has been added for the Q3 and X3 models. NM Remote Reconstruction is now possible on the optional myExam Satellite. The following scanning improvements have been made: • Updates for image visualization • Updates to patient positioning aides. • Automatic unload improvements. The following reconstruction improvements have been made: • Non-distortion Tomo improvements have been added.	N/A

	• Detector Orbit Recon Mask has been introduced. • Apply Registration Tool has been added. The following General Software Improvements have been added: • NM Raw Data Disk Space Icon has been added. • Updates have been made to the Broad Quantification User Interface.	
Export updates	Same	Same
CT Software updates	myExam Satellite CT Remote Reconstruction. Additional features as included in SOMATOM VB10 K233650.	N/A
Connectivity	Same	Same
SPECT Detectors	Same	Same
SPECT Gantry	Same	Same
CT Gantry updates	No changes as compared to SOMATOM VB10 K233650.	N/A
Detector Performance and Collimator Specifications	Same	Same
GUI Changes	Same	Same
3 rd Party Software Options	Cedars (K172609) Corridor 4DM (K101279)	Cedars (K172609) Corridor 4DM (K101279)

Intended Use:

The Symbia Pro.specta systems are radiological imaging systems that combines a single photon emission computed tomography (SPECT) camera system for nuclear medicine images, and a computed tomography (CT) camera system for x-ray images.

The SPECT system is intended to detect the location and distribution of gamma ray radionuclides in the body and produce cross-sectional images through computer reconstruction of the data, and the CT system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. The nuclear medicine images and the x-ray images may be registered and displayed in a fused format (overlaid in the same orientation) for the anatomical localization of the nuclear

medicine data (that is, distribution of radiopharmaceuticals). The SPECT and CT portions of the system may be used independently or in combination, and may include signal analysis and display equipment, patient and equipment support, radionuclide anatomical markers, component parts, and accessories. The SPECT and CT images may be transferred to other systems for radiation therapy planning or additional uses.

Indications for Use:

The Symbia Pro.specta systems are intended for use by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning or additional uses.

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Software: The SPECTsyngo software is an acquisition, display and analysis package intended to aid the clinician in the assessment and quantification of pathologies in images produced from SPECT, PET, CT, and other imaging modalities.

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*As defined by professional medical societies. 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.

There are no known contraindications.

Technological Characteristics:

Performance Testing:

Performance testing for the CT subsystem was included in the premarket notification for the CT subsystems (K233650) and there have been no changes affecting this testing.

Each CT subsystem is tested and passes the Applicable Performance

Standards prior to shipment:

- 21 CFR 1020.30 (a) Applicability
- 21 CFR 1020.30 (b)(36)(iii)-(v) Technique Factors
- 21 CFR 1020.30 (b)(58)-(62) CT, Scan, Scan Time, Tomogram, Dose
- 21 CFR 1020.30 (h)(3)(vi)-(viii) Information to be provided for users
- 21 CFR 1020.33 Computed Tomography (CT) equipment
- 21 CFR 1040.10 Laser Products
- 21 CFR 1040.11 Specific purpose laser products

Symbia Pro.specta VA30A systems are designed in accordance with the 60601-1 series including all relevant collateral standards general (IEC 60601-1, 1-2, 1-3, etc.) and specific (IEC 60601-2-44). Performance testing is conducted according to NEMA NU-1. All Performance testing met the predetermined acceptance values.

Detector Specifications		
Intrinsic spatial resolution - Tc99m	SPECT	3/8"
FWHM in CFOV	SPECT	≤3.84 mm
FWHM in UFOV	SPECT	≤3.94 mm
FWTM in CFOV	SPECT	≤7.54 mm
FWTM in UFOV	SPECT	≤7.74 mm
Intrinsic spatial linearity - Tc99m	SPECT	
Differential in CFOV	SPECT	≤0.24 mm
Differential in UFOV	SPECT	≤0.24 mm
Absolute in CFOV	SPECT	≤0.44 mm
Absolute in UFOV	SPECT	≤0.7 mm
Intrinsic energy resolution	SPECT	
FWHM in CFOV	SPECT	≤9.9%
Intrinsic flood field uniformity (uncorrected) - Tc99m	SPECT	
Differential in CFOV	SPECT	≤2.5%
Differential in UFOV	SPECT	≤2.7%
Integral in CFOV	SPECT	≤2.9%
Integral in UFOV	SPECT	≤3.7%

Existing NEMA detector and collimator performance specifications do not change between the commercially available Symbia Pro.specta VA20A Family and proposed Symbia Pro.specta VA30A systems. There are no changes in the system design that could impact the SPECT performance specifications and the commercially available specifications still apply.

Bench testing performed on the CT subsystem is conducted in accordance with IEC 60601-2-44 and in accordance with US regulations including 21 CFR 1020.33, Computed Tomography (CT) equipment. This is unchanged from the commercially available SOMATOM go CT systems (K233650).

Risk analyses performed at Siemens Medical Solutions USA; Inc. are in compliance with the requirements of:

- IEC/ISO 14971 Medical Devices – Application of Risk Management to Medical Devices
- IEC 62304 Medical Device Software – Software Life-cycle Processes

There is no significant difference in the risks imposed by this system and the risks associated with the predicate devices. The product Risk Management Team has reviewed and verified that all risks identified in the Symbia Pro.specta VA30A Product Risk Analysis has been adequately mitigated and the individual and overall residual risks are reduced as far as possible.

Verification and validation of Siemens software is performed in accordance with documented procedures, test plans and specifications. Traceability of the requirements specified in the requirement specifications and functional specifications is ensured during component integration, software verification, and system testing.

System and System Integration testing (validation) was carried out for all features of the project, and all planned test cases were executed.

Verification and Validation is performed to:

- ensure the functionality described in the specifications are met,
- ensure the quality in the planning documentation is adhered to,
- ensure mitigations required by risk analysis are implemented, and appropriate
- identify additional issues that may be related to patient / operator safety, or effectiveness
- assure that the specifications are appropriate to fulfill the intended use of the system.

Safety and Effectiveness:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product.

Cybersecurity information in accordance with FDA Guidance documents issued on September 27, 2023, has been provided. The Symbia Pro.specta VA20A systems software has specific cybersecurity controls to prevent unauthorized access, modifications, misuse or denial of use.

Additionally, controls are enabled to prevent the unauthorized use of information that is stored, accessed or transferred between the Symbia Pro.specta VA20A systems and external devices.

Siemens Medical Solutions, USA Inc. adheres to recognized and established industry standards such as IEC 60601-1 series and 21 CFR 1020.30 and 21 CFR 1020.33 to minimize electrical, mechanical and radiation hazards.

Symbia Pro.specta VA30A systems conform to applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as required by the respective SPECT FDA Guidance Documents. SPECT detector and CT performance is conducted according to NEMA NU-1, and the performance does not change from the predicate device.

Verification and validation of Siemens systems is performed in accordance with documented procedures, design and code reviews, test plans and specifications. Traceability of the requirements specified in the requirement specifications and functional specifications is ensured during component integration, software validation and system testing.

Statement Regarding Substantial Equivalence:

Symbia Pro.specta VA30A systems are based on the commercially available Symbia Pro.specta VA20A systems and have the same indications for use as well as utilizes the same fundamental scientific technology as the predicate device. The software updates pose no new issues of safety and / or efficacy. Siemens considers the Symbia Pro.specta VA30A systems to be as safe and effective as the commercially available predicate device with substantially equivalent performance.