May 17, 2023

Siemens Medical Solutions USA, Inc.
% Tabitha Estes
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

Re: K231102
Trade/Device Name: Symbia Pro.specta VA20A Family
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: April 18, 2023
Received: April 18, 2023

Dear Tabitha Estes:

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); 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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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

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)*

K231102

Device Name
Symbia Pro.specta VA20A Family

Indications for Use *(Describe)*

The Siemens Symbia Pro.specta VA20A Family is 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.

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

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter:	Tabitha Estes 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) 804 - 4553
Date of Submission:	April 18th, 2023

Identification of the product

Device Proprietary Name:	Symbia Pro.specta VA20A 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 VA10A 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:	K212604

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:	K211373

Reference Device:

Device Name and 510(k) numbers:	MI View&Go VA20A
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:	K222172

Device Description:

The Siemens Symbia Pro.specta VA20A 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 VA20A Family maintains the same intended use and indications for use as the commercially available Symbia Pro.specta VA10A family (K212604).

Symbia Pro.specta VA20A 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 VA20A release is the product name for the addition of additional features to the approved Symbia Pro.specta VA10A Family (K212604). The Symbia Pro.specta VA20A devices are based on the Symbia Pro.specta VA10A Family. The difference lies in the additional features/changes. The Intended Purpose and fundamental scientific technology remain unchanged.

Proposed New Features for Symbia Pro.specta VA20A Family:

- my Exam Satellite

Other changes:

- improvement of CT topogram planning
- enhanced QCI (Quality Control Image) projections
- bed height after reconfigure
- GUI change for radiopharmaceutical configuration
- Nuclear medicine raw data export
- GUI and configuration change for scan end beep
- Auto Export Tool improvements

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

Features	**Symbia Pro.specta VA20 (Subject Device)**	**Symbia Pro.specta VA10 (Predicate Device)**
Intended/Indication For Use	Same	Same
Biocompatibility	Same	Same
Productivity Features	Same	Same
Optional Pallets/Accessories/Collimators	Same	Same
MI View&GO updates	Inclusion of MI Neurology, Auto Lung 3D and syngo.MBF as well as incremental improvements. All changes are included in K222172.	N/A
Operating System	Same	Same
Computer Systems additions	myExam Satellite has been added as an additional workplace computer.	N/A
Scan Planning Updates	For SPECT-first hybrid workflows and CT-first hybrid workflows where planning is done by positioning the patient under the NM detectors, the topogram planning has been updated.	N/A
SPECT Software updates	TrueCalc has been added as a Quantification method for the Symbia Pro.specta Q3. Enhanced QCI Projections has been implemented. This option will allow the user to change the projection image if they prefer different parameters from the default behavior. Additional DICOM attributes have also been included with this software update. A change has also been made to the software on bed height control. The bed will be restored to the position it was in prior to reconfiguration	N/A

	(applies to 180, 90, 76 and CT).	
Export updates	Updates have been made to the Auto Export Tool to streamline the workflow. Also, workflow improvements to data export has been made so that the user can send SPECT raw data and DICOM data to a file system with one export tool.	N/A
CT Software updates	ADMIRE (Advanced Modelled Iterative Reconstruction) for the Symbia Pro.specta X7. Additional features as included in SOMATOM VA40 K211373.	N/A
Connectivity	Same	Same
SPECT Detectors	Same	Same
SPECT Gantry	Same	Same
CT Gantry updates	No changes as compared to SOMATOM VA40 K211373.	N/A
Detector Performance and Collimator Specifications	Same	Same
GUI Changes	Updates have been made to the GUI for updates to the radiopharmaceutical configuration and the scan end beep.	N/A

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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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.

Technological Characteristics:

Performance Testing:

Performance testing for the CT subsystem was included in the premarket notification for the CT subsystems (K211373) 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 VA20A 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 VA10A Family and proposed Symbia Pro.specta VA20A 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 (K211373).

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 VA20A 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 October 2, 2014, 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 VA20A 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 VA20A systems are based on the commercially available Symbia Pro.specta VA10A 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 VA20A systems to be as safe and effective as the commercially available predicate device with substantially equivalent performance.