Siemens Medical Solutions USA, Inc.
% Ms. Cynthia Busch
Regulatory Affairs Specialist
2501 N Barrington Road
HOFFMAN ESTATES IL 60192

March 20, 2020

Re: K200474
Trade/Device Name: Symbia 6.7
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: February 24, 2020
Received: February 26, 2020

Dear Ms. Busch:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200474

Device Name
Symbia 6.7

Indications for Use *(Describe)*

The Siemens Symbia series 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 and interventional radiology procedures.

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 take 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 syngo MI Applications software is a 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.

The following statement applies only to Siemens Symbia T16, Symbia Intevo 16, and Symbia Intevo Bold systems:
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

as required by 21 CFR Part 807.87(h) and 21 CFR Part 807.92(c)

K200474

Identification of the Submitter

Submitter:	Cynthia Busch Regulatory Technical Specialist Siemens Medical Solutions USA, Inc. 2501 N. Barrington Road Hoffman Estates, IL 60192 USA
Name / Address of Manufacturer:	Siemens Medical Solutions USA, Inc Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA
Telephone Number:	(847) 643-6818
Date of Submission:	February 24, 2020

Identification of the product

Device Proprietary Name:	Symbia 6.7
Common Name:	Single-photon emission computed tomography (SPECT) system Computed Tomography (CT) System
Classification Name:	Emission Computed Tomography per 21 CFR 892.1200
Product Code:	KPS (primary) JAK (secondary)
Classification Panel:	Radiology
Class:	II

Marketed Devices to which Equivalence is claimed

Primary Predicate:

Device	Manufacturer	510(k) Number	Device Classification Name	Regulation
Symbia 6.5	Siemens Medical Solutions USA, Inc	K162337	Emission Computed Tomography	21 CFR 892.1200

Secondary Predicate:

Device	Manufacturer	510(k) Number	Device Classification Name	Regulation
Symbia Intevo Bold	Siemens Medical Solutions USA, Inc	K162483	Emission Computed Tomography	21 CFR 892.1200

Reference Predicate Devices:

Device	Manufacturer	510(k) Number	Device Classification Name	Regulation
SOMATOM Scope/Scope Power, and SOMATOM Emotion 16 with VC50	Siemens Medical Solutions USA, Inc	K183548	Computed Tomography X-Ray System	21 CFR 892.1750

Device	Manufacturer	510(k) Number	Device Classification Name	Regulation
Symbia 5.0	Siemens Medical Solutions USA, Inc	K131634	Emission Computed Tomography	21 CFR 892.1200

Device Description:

The Siemens Symbia systems consist of Single Photon Emission Computed Tomography (SPECT) scanners and integrated hybrid X-Ray Computed Tomography (CT) and SPECT scanners. 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.

All systems implement a new software version *syngo* MI Applications VB20A.

Symbia 6.7 Family		
SPECT only systems	Symbia E Single	variable angle, single detector gamma camera
	Symbia E Dual	variable angle, dual detector gamma camera
	Symbia S	variable angle dual detector SPECT system
	Symbia Evo	variable angle dual detector SPECT system
	Symbia Evo Excel	variable angle dual detector SPECT system
SPECT/CT Systems	Symbia T	SPECT/CT system with non-diagnostic CT support for only attenuation correction and anatomical localization
	Symbia T2, T6, T16	a variable angle dual detector SPECT with a 2, 6, or 16-slice spiral CT to give the system full functionality for all SPECT-only, xSPECT, or stand-alone CT diagnostic applications
	Symbia Intevo Excel	SPECT/CT system with non-diagnostic CT support for only attenuation correction and anatomical localization
	Symbia Intevo 2, Intevo 6, Intevo 16, Intevo Bold	variable angle dual detector SPECT and 2, 6, or 16-slice spiral CT to give the system full functionality for all SPECT-only, xSPECT, or stand-alone CT diagnostic applications

Figure 1: Symbia models

Modifications in Symbia 6.7 include:

a) Software: Modifications to xSPECT features and other software updates:

- update to organ processing features:
    a. gastric retention addition:
    b. renal processing improvement.
- Addition of SPECT Dose Reporting
- xSPECT Quantification: expansion of commercially available xSPECT Quant (Symbia 5.0 K131634) to support Absolute Quantification of additional isotope I-131.
- upgrade to Windows® 10 Operating System for syngo MI Applications VB22A including:
    a. updated version of syngo software; VI20
    b. Somaris 5 VC50 (K183548), 3rd party software applications; Corridor 4DM, Cedars, Scenium, and TrueD are updated for Windows 10 compatibility.

b) Hardware:

Updated computer models for obsolescence

Intended Use:

The Symbia Intevo Excel, Symbia Intevo series and Symbia T series are radiological imaging systems that combine 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 Symbia E series, Symbia S, Symbia Evo, and Symbia Evo Excel systems are SPECT camera systems.

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 supports, 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 Siemens Symbia series 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 and interventional radiology procedures.

SPECT: To detect or image the distribution of radionuclides in the body or organ, using the following techniques: planar imaging, whole body imaging, tomographic imaging for isotopes with energies up to 588keV

CT: The CT component is intended 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.

SPECT+CT: Perform CT scans and nuclear imaging studies with the same instrument. To obtain attenuation corrected images and to provide registration of anatomical and physiological images within the patient's anatomy.

Software: The MI Applications software is a display and analysis package intended to aid the clinician in the assessment and quantification of pathologies taken from SPECT, PET, CT and other imaging modalities.

The following statement applies only to Siemens Symbia T16, Symbia Intevo 16, and Symbia Intevo Bold systems:
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.

Technological Characteristics:

Symbia 6.7 systems are based on the commercially available Symbia 6.5 (K162337) and Symbia Intevo Bold (K162483) . The software updates are based on the same fundamental technology of the xSPECT quantification in Symbia SPECT/CT predicate components. SPECT detector, existing collimators, and CT performance specifications do not change between the commercially available Symbia 6.5 systems and Symbia 6.7 systems.

Performance Testing:

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

Symbia 6.7 is designed in accordance with the 60601-1 series including all relevant collateral standards general and specific (see standards table in Safety and Effectiveness section). Collimator performance testing is conducted according to NEMA NU-1:2018. All Performance testing met the predetermined acceptance values.

Figure 2 below Depicts Detector Specifications which are valid for Symbia 6.7 and published in the predicate device Symbia 6.5 data sheet. Specifications have not changed from the predicate device.

Detector Specifications	3/8”
Intrinsic Spatial Resolution	
FWHM in CFOV	≤3.8 mm
FWHM in UFOV	≤3.9 mm
FWTM in CFOV	≤7.5 mm
FWTM in UFOV	≤7.7 mm
Intrinsic Spatial Linearity	
Differential in CFOV	≤0.2 mm
Differential in UFOV	≤0.2 mm
Absolute in CFOV	≤0.4 mm
Absolute in UFOV	≤0.7 mm
Intrinsic Energy Resolution	
FWHM in CFOV	≤9.9%
Intrinsic Flood Field Uniformity (Uncorrected)	
Differential in CFOV	≤2.5%
Differential in UFOV	≤2.7%
Integral in CFOV	≤2.9%
Integral in UFOV	≤3.7%
Multiple Window Spatial Registration	≤0.6 mm
Intrinsic Count Rate Performance in Air	
Maximum Count Rate	310 kcps
Intrinsic Spatial Resolution at 75 kcps	
FWHM in UFOV	≤4.1 mm
FWTM in UFOV	≤7.8 mm
Intrinsic Flood Field Uniformity at 75 kcps	
Differential in CFOV	≤2.5%
Differential in UFOV	≤2.7%
Integral in CFOV	≤2.9%
Integral in UFOV	≤3.7%
System Spatial Resolution Without Scatter (LEHR at 10 cm)	

FWHM in CFOV	≤7.5 mm
FWTM in CFOV	≤13.6 mm
System Spatial Resolution With Scatter (LEHR at 10 cm)	
FWHM in CFOV	≤8.3 mm
FWTM in CFOV	≤18.6 mm
System Planar Sensitivity (LEHR at 10 cm)	
Absolute	202 cpm/µCi
System Planar Sensitivity (ME at 10 cm)	
Absolute 111In	430 cpm/µCi
Average Volume Sensitivity per axial centimeter	
LEHR Tc99m	12,000 (cts/sec)/(MBq/cm²)
Detector-Detector Sensitivity Variation (LEHR, 99mTc)	≤5.0%
Whole-Body System Spatial Resolution Without Scatter at 10 cm/min Scan Speed (LEHR at 10 cm)	
FWHM Perpendicular	≤7.5 mm
FWHM Parallel	≤7.9 mm
FWTM Perpendicular	≤14.0 mm
FWTM Parallel	≤14.2 mm

Figure 2 Detector Specifications

Image Quality

Figure 3 below shows NEMA performance testing results demonstrate accurate quantification in phantoms for all the isotopes and collimators tested. NEMA and high count performance results meet specifications.

Summary of Quantitative accuracy specifications*	
Quantitative error Tc99m LEHR/LPHR	≤10%
Quantitative error I123 LPHR/MELP	≤10%
Quantitative error In111 MELP	≤10%
Quantitative error Lu177 MELP	≤10%
Quantitative error Lu177 MELP at 310kcps**	≤10%
Quantitative error I131 HE **	≤10%

Figure 3 Quantitative Accuracy Specifications

* In phantoms for objects with negligible partial volume effect
** incident count rate

The quantitative error for all isotopes with the collimators is smaller or equal to 10%, and met the predefined acceptance criteria.

SPECT detector, existing collimators, quantification supported with additional isotopes and CT performance specifications do not change the fundamental technology between the commercially available Symbia 6.5 systems and Symbia 6.7 systems. There are no changes in the system design that could impact the SPECT performance specifications, and the commercially available NEMA NU1:2018 specifications.

Performance testing for the CT subsystem was included in the original premarket notification for the CT subsystems and there have been no modifications from the original FDA clearance via CT 510k Somaris 5 VC50 (K183548) that affect device performance.

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.

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.

Siemens claims compliance with the following product standards for the Symbia systems:

- IEC 60601-1: 2005+ A1:2012
- IEC 60601-1-2: 2014
- IEC 60601-1-3: 2013
- IEC 60601-1-6:2010 +A1:2013
- IEC 60601-2-28:2010
- IEC 60601-2-44: 2009 + A1:2012
- IEC 61223-2-6:2006
- IEC 61223-3-5:2004
- IEC 62366-1:2015
- IEC 62304:2015
- NEMA XR 25: 2010
- NEMA XR 28: 2013
- NEMA PS3.1-3.20: 2016

Symbia 6.7 conforms 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 NU1:2018, and the performance does not change from the predicate device.

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

Cybersecurity features have been assessed according to FDA Guidance issued October 2, 2014 'Content of Premarket Submissions for Management of Cybersecurity in Medical Devices'.

The Symbia 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 systems and external devices.

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.

Substantial Equivalence:

Symbia 6.7 has the same intended use and utilizes the same fundamental scientific technology as the predicate device. There have been no changes implemented in the modifications of the Symbia systems that impact the fundamental technology or the indications for use. Siemens considers Symbia 6.7 to be as safe, as effective, and with performance substantially equivalent to the commercially available predicate device.