DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 8, 2016

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

Re: K162337
Trade/Device Name: Symbia 6.5
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: August 22, 2016
Received: August 23, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041

or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162337

Device Name
Symbia 6.5

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.

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) and 21 CFR Part 807.92(c)

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) 304-7095
Fax Number:	(847) 304-6023
Date of Submission:	August 19, 2016

Identification of the product

Device Proprietary Name:	Symbia 6.5
Common Name:	Single-photon emission computed tomography (SPECT) system Computed Tomography (CT) System
Classification Name:	Emission Computed Tomography per 21 CFR 892.1200 Computed Tomography X-Ray System per 21 CFR 892.1750
Product Code:	KPS and JAK
Classification Panel:	Radiology
Class:	II

Marketed Devices to which Equivalence is claimed

Predicate:

Device Proprietary Name:	Symbia 6.0
Manufacturer:	Siemens Medical Solutions USA, Inc
Product Code:	KPS and JAK
Device Class:	II
510(k) Number:	K142006

Reference Device(s):

Device Name(s):	CT SOMARIS/5 VC30
510(k) Number(s):	K151752

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 6.0 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 series	a variable angle dual detector SPECT with a 2, 6, or 16-slice spiral CT
	Symbia Intevo Excel	SPECT/CT system with non-diagnostic CT support for only attenuation correction and anatomical localization
	Symbia Intevo Series	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

Modifications in Symbia 6.5 include:

- Upgraded software *syngo* MI Applications VB20A which incorporates expansions of commercially available xSPECT Quantification (Symbia 5.0 K131634)
- Implementation of commercially marketed CT software, (K151752, 'CT SOMARIS/5 VC30')
- Integration of commercially marketed software application *syngo* TrueD (K101749) for viewing, manipulation, 3D visualization and comparison of medical images from multiple imaging modalities.
- Hardware upgrade; four additional touchpad sensors to cover detectors' light rails and L-arms

Intended Use:

The Symbia Intevo Excel, Intevo series and 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, Evo, and 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.

Technological Characteristics:

Symbia 6.5 systems are based on the commercially available Symbia 6.0 (K142006). 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 6.0 systems and Symbia 6.5 systems. The *syngo* TrueD software application, incorporated into the updated software, is commercially available (K101749).

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 6.5 is 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-1:2012. All Performance testing met the predetermined acceptance values.

Table 1 and 2 depict quantitative accuracy of 3/8" and 5/8"
Acceptance criteria: The absolute quantification accuracy of the system shall be within 10% in phantoms for objects larger than three times the system resolution when acquired for count rates up to 160 kcps.

3/8''	**Acceptance Criteria**	**Deviation from true (%)**
Phantom	<=10%	Pass

Table 1: NEMA IEC Phantom
System type: Symbia Intevo. SW version VB20A

5/8''	**Acceptance Criteria**	**Deviation from true (%)**
Phantom	<=10%	Pass

Table 2: NEMA IEC Phantom
System type: Symbia Intevo. SW version VB20A

Conclusion:

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

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.

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.

Symbia 6.5 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 NU1:2012, and the performance does not change from the predicate device.

Substantial Equivalence:

Symbia 6.5 has the same intended use and utilizes the same fundamental scientific technology as the predicate device. Siemens considers Symbia 6.5 to be as safe, as effective, and with performance substantially equivalent to the commercially available predicate device.