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

January 9, 2017

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

Re: K162483
Trade/Device Name: Symbia Intevo Bold
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: November 28, 2016
Received: November 29, 2016

Dear Mr. 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)*

K162483

Device Name
Symbia Intevo Bold

Indications for Use *(Describe)*

The Siemens Symbia Intevo Bold 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.

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)

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:	September 2, 2016

Identification of the product

Device Proprietary Name:	Symbia Intevo Bold
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 Intevo 16
Manufacturer:	Siemens Medical Solutions USA, Inc.
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
Device Class:	II
510(k) Number:	K142006

Reference Device(s):

Device Name(s):	SOMATOM Scope Power (with SOMARIS/5 VC30)
Manufacturer:	Siemens Medical Solutions USA, Inc.
Classification Name:	Computed Tomography X-Ray System per 21 CFR 892.1750
Product Code:	JAK
Device Class:	II
510(k) Number(s):	K151749

Reference Device(s):

Device Name(s):	Symbia 5.0
Manufacturer:	Siemens Medical Solutions USA, Inc.
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
Device Class:	II
510(k) Number(s):	K131634

Device Description:

The Siemens Symbia Intevo Bold 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.

Symbia Intevo Bold implements software version *syngo* MI Applications VB20A.

Modifications include:

1) Incorporation of the commercially available SOMATOM Scope Power CT system (K151749)

2) Software updates include modifications to support features available with the CT and SPECT subsystems

3) Expansion of commercially available xSPECT Quant (Symbia 5.0 K131634) to support quantification of additional isotopes

4) Four additional touchpad sensors to cover detectors' light rails and L-arms.

Commercially available xSPECT Quant (Symbia 5.0 K131634) was expanded to support quantification of additional isotopes such as I-123 and In-111. For these isotopes, dose calibrator independent quantification is enabled by a NIST traceable sensitivity calibration method. In addition, cross calibration capabilities were added to remove dose calibrator biases and variations in SUV calculations. The system allows cross calibration of multiple dose calibrators and, once calibrated, automatically adjusts for their biases.

In addition to dose calibrator independent quantification for I-123 and In-111 support for dose calibrator dependent quantification was added for a broad range of SPECT isotopes and collimators (Broad Quantification). Dose calibrator dependent quantification neither supports NIST traceable calibration nor cross calibration and relies on sensitivity measurements based on a local dose calibrator.

Intended Use:

The Symbia Intevo Bold is a radiological imaging system 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 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 Intevo Bold 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 Intevo Bold is based on the commercially available Symbia Intevo 16 of the Symbia SPECT/CT scanners (K142006, Symbia 6.0). Symbia Intevo Bold incorporates the SOMATOM Scope Power CT (K151749). Updates to xSPECT quantitative software are based on the same fundamental technology of the xSPECT quantification in Symbia SPECT/CT predicate components. The SPECT detector, existing collimators, and CT performance specifications do not change between the commercially available Symbia Intevo 16 and proposed system, Symbia Intevo Bold.

Essential Characteristics Comparison with Predicate Device:

Feature / Characteristic	Proposed Device: Symbia Intevo Bold	Predicate Device: Intevo 16	Difference
Scanner Models	Symbia Intevo Bold	Symbia Intevo 16	New model Symbia Intevo Bold, the subject of this 510K application
Target Population	General use	General use	Same
Tracer Support	Tl-201, Xe-133, Co-57, Tc-99m, I-123, In-111, Ga-67, I-131, F-18.	Tl-201, Xe-133, Co-57, Tc-99m, I-123, In-111, Ga-67, I-131, F-18	Same
Collimators	LEHS, LEAP, LEHR, LEUHR, LEFB, ME, HE, UHE, Pinhole, SMARTZOOM, LPHR	LEHS, LEAP, LEHR, LEUHR, LEFB, ME, HE, UHE, Pinhole, SMARTZOOM, LPHR	Same
Optional Pallets	Pediatric, Scintimammography, Radiation therapy	Pediatric, Scintimammography, Radiation therapy	Same
Accessories	Head Holder, Body Wrap, Arm Rest, Cushions	Head Holder, Body Wrap, Arm Rest, Cushions	Same
Software Version	syngo MI Applications VB20	syngo MI Applications VB10	MI Applications upgrade for new features, updates and defect fixes.
Somaris Version (CT Software)	VC30	VC20	CT software (commercially available for Scope Power (K151749) upgrade due to new features and updates.

CT Software Features	CARE Dose 4D, SureView, Workstream4D, HeartView CT, syngo Care Bolus, syngo Pulmo, syngo Fly through, syngo Calcium Scoring, Asynchronous Recon, Multiplanar Reconstruction (MPR), Syngo 3D SSD,FAST Planning, FAST Spine, IRIS, Fast kV, Fast 3D Align, multi-series CTAC, SAFIRE, iMAR, IVR, SSDE	CARE Dose 4D, SureView, Workstream4D, HeartView CT, syngo Care Bolus, syngo Pulmo, syngo Fly through, syngo Calcium Scoring, Asynchronous Recon, Multiplanar Reconstruction (MPR), Syngo 3D SSD,FAST Planning, FAST Spine, IRIS.	• Fast kV- CT feature allows the system to automatically adapt mAs once the scan kV has been set for a patient in order to keep the right correlation between these scan parameters. • Fast 3D Align - CT feature which provides automatic centering and aligning of the reconstruction volumes. • Multi series CT AC- enables the use of multiple CT scans for attenuation correction • SAFIRE – (Sinogram Affirmed Iterative Reconstruction) a CT iterative reconstruction method which helps lower the noise and enhance sharpness in CT images. • iMAR- Metal Artifact Reduction Metal Artifact Reconstruction software designed to reduce metal artifacts caused by large and/or dense metal objects in computed tomography images. • IVR- Interleaved Volume Reconstruction uses measured data by reconstructing overlapping slices from up to 32 slices. This improves the spatial resolution in the Z-direction.

Feature / Characteristic	Proposed Device: Symbia Intevo Bold	Predicate Device: Intevo 16	Difference
Advanced Reconstruction	IQ•SPECT Reconstruction xSPECT Reconstruction	IQ•SPECT Reconstruction xSPECT Reconstruction	Same
Quantification	xSPECT Quantification (Bq/ml) Broad Quantification PET SUV Quantification (Bq/ml)	xSPECT Quantification (Bq/ml) PET SUV Quantification (Bq/ml)	xSPECT Quantification expands features to include standardized quantification of isotopes In-111 and I-123 and software improvements to support the detectors' high-count rate quantitative imaging. Broad Quantification is an expanded offering of xSPECT Quantification for Tc99m from commercially marketed Symbia 5.0 (K131634).

Siemens believes that the Symbia Intevo Bold is substantially equivalent to the predicate device. There are no differences in the Indications for Use or Fundamental Technological Characteristics of the Symbia Intevo Bold as compared to the commercially available Symbia Intevo 16. Additionally, there have been no changes that raise any new issues of safety and effectiveness as compared to the predicate devices.

Performance Testing:

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 (K151749) that affect device performance.

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 Intevo Bold 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 of this document).

Performance testing is conducted according to NEMA NU-1:2012 including:

- intrinsic spatial resolution;
- intrinsic spatial linearity
- intrinsic energy resolution;
- intrinsic flood field uniformity;
- multiple window spatial registration
- intrinsic count rate performance in air;
- system spatial resolution with LEHR
- SPECT reconstructed spatial resolution

- System Performance Testing at high count rates:
  - Intrinsic flood field uniformity at 25% busy time
  - Intrinsic energy resolution at 25% busy time
  - Energy peak position stability
  - System spatial resolution at 25% busy time

Testing includes image quality performance and integration testing for the new CT sub-system. All Performance testing met the predetermined acceptance values.

Broad Quantification and xSPECT Quant Testing :

The absolute quantitative accuracy of xSPECT Quant was verified in phantoms for the isotope-collimator combinations shown in Table 1. The acceptance criterion for xSPECT Quant is a quantitative error of smaller or equal to 10% in reference to the National Institute of Standards and Technology (NIST), i.e. when the system is calibrated with the NIST traceable precision source.

The reproducibility of dose calibrator dependent Broad Quantification was verified for isotope collimator combinations shown in Table 2. The reproducibility was verified to be within 10%.

Standard quality control phantoms such as the NEMA NU 2-1994 Test Phantom and the NEMA IEC Body Phantom were used for verification testing. All tests were performed using standard clinical acquisition and reconstruction protocols. All tests met specifications.

Isotope	Collimator	Acceptance: Quantitative error	Verification Result
Tc99m	LEHR	<= 10%	passed
Tc99m	LPHR	<= 10%	passed
I123	LPHR	<= 10%	passed
I123	MELP	<= 10%	passed
In111	MELP	<= 10%	passed

Table 1: Quantitative accuracy verification of xSPECT Quant

Isotope	Collimator	Acceptance: reproducible within	Verification Result
Ga67	MELP	<= 10%	passed
I131	HE	<= 10%	passed

Table 2: Verification of quantitative reproducibility

Conclusion of Performance Testing:
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 Intevo Bold 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 of the new device is substantially equivalent to the predicate device.

Standard	
IEC 60601-1	2005 (R)2012 and C1:2009/ (R)2012
IEC 60601-1-2	2007
IEC 60601-1-3	2013
IEC 60601-1-6	2010
IEC 60601-2-28	2010
IEC 60601-2-44	2012
IEC 60825-1	2007
IEC 60950-1	2006
IEC 61223-2-6	2006
IEC 62304	2006
IEC 62366	2007

Standard	
NEMA NU-1	2012
NEMA XR-25	2010
NEMA XR-28	2013
NEMA XR-29	2013
ISO 10993-1	2009
EN ISO 14971	2012
EN ISO 13485	2012

Substantial Equivalence:

Symbia Intevo Bold is based on the commercially available Symbia Intevo 16 and has the same intended use and utilizes the same fundamental scientific technology as the predicate device. The software updates are based on predicate device features and commercially available software applications which pose no new issues of safety and / or efficacy. Siemens considers Symbia Intevo Bold to be as safe, as effective, and with performance substantially equivalent to the commercially available predicate device.