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

November 17, 2017

Re: K173023
Trade/Device Name: Symbia T16, Symbia Intevo 16 and Symbia Intevo Bold
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and JAK
Dated: September 27, 2017
Received: September 28, 2017

Dear Ms. 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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30120120
See *PRA Statement below.*

510(k) Number *(if known)*
K173023

Device Name
Symbia T16, Symbia Intevo 16 and Symbia Intevo Bold

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: 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 syngo 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 the 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)*

X 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.

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510(k) Summary

as required by 21 CFR Part 807.92

Identification of the Submitter

Submitter:	Tabitha Estes Regulatory Affairs Specialist Siemens Medical Solutions USA, Inc. Molecular Imaging 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)218-2421
Fax Number:	(865)218-3019
Date of Submission:	September 27th, 2017

Identification of the product

Device Proprietary Name:	Symbia T16 SPECT/CT	Symbia Intevo 16 SPECT/CT	Symbia Intevo Bold SPECT/CT
Common Name	Single-Photon Emission Computed Tomography (SPECT) System		
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200 Computed Tomography X-Ray System per 21 CFR 892.1750		
Product Code:	90 KPS and 90 JAK		
Classification Panel:	Radiology		
Device Class:	Class II		

Marketed Devices to which Equivalence is claimed

Predicate:

Device Proprietary Name: SOMATOM CT Scanners

Manufacturer: Siemens Medical Solutions USA, Inc.

Product Code: 90 JAK

Device Class: Class II

510(k) Number: K142955

Reference Devices:

Device Proprietary Name:	Symbia T16 SPECT/CT	Symbia Intevo 16 SPECT/CT	Symbia Intevo Bold SPECT/CT
510(k) :	K162337	K162337	K162483

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.

The Symbia SPECT/CT systems that are the subject of this Premarket Notification are identical in design, material, functionality, technology and energy source to the commercially available Symbia SPECT/CT systems.

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 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.

This submission was made to support an additional indication for use related to lung cancer screening within the subset of the overall intended use of the Symbia T16, Symbia Intevo 16 and Symbia Intevo Bold SPECT/CT scanners:

> The following statement is only applicable 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.

This revised indication for use is cleared for the standalone SOMATOM CT systems (K142955) that are incorporated into the SPECT/CT systems.

In accordance with guidance document "Guidance for Industry. General/Specific Intended Use" issued November 4, 1998, and presentation "FDA/MITA Meeting on LDCT Lung Cancer Screening", the modified more specific indication for use does not alter the intended use for the legally marketed predicate devices with a general indication for use, nor does it alter the intended diagnostic effect in comparison to the predicate devices.

Based on the analysis conducted within the original 510(k) for the SOMATOM CT systems (K142955) and the integration of the CT subsystem, without altering the technological characteristics, into the Symbia SPECT/CT systems, the more specific use of low dose lung cancer screening is a subset of the general use rather than a new intended use. Further, the updated specific indication is substantially equivalent to the inclusion of this specific indication within the predicate device.

Revised 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

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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 is only applicable 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.

Performance Testing / Safety and Effectiveness:

The Symbia SPECT/CT systems that are the subject of this Premarket Notification are identical in design, material, functionality, technology and energy source to the commercially available Symbia SPECT/CT systems. No additional performance testing beyond what was cleared in the original Premarket Notifications is required.

CT Testing in accordance with the requirements of the following FDA Performance Standards for Ionizing Radiation Emitting Products and Light emitting products for CT equipment with a laser localizer was performed and documented in a Dosimetry and Imaging Performance Report. Further, 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

The Symbia SPECT/CT systems were designed in accordance with Design Controls and in accordance with the following FDA recognized standards:

- Recognition Number 19-1: IEC 60601-1-2 Edition 3: 2007-03
- Recognition Number 19-4: AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012
- Recognition Number 5-67: AAMI ANSI IEC 62366:2007/(R)2013
- Recognition Number 12-256: IEC 60601-2-44 Edition 3.1 2012-09
- Recognition Number 12-269: IEC 60601-1-3 Edition 2.1 2013-04
- Recognition Number 5-40: ISO 14971 Second Edition 2007-03
- Recognition Number 13-79: IEC 62304 Edition 1.1 2015-06
- Recognition Number 12-265: NEMA NU 1
- Recognition Number 12-225: NEMA XR 25
- Recognition Number 12- 270: NEMA 61223-3-5 First Edition 2004
- Recognition Number 12-226: NEMA 61223-2-6 Second Edition: 2006

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.

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.

Technical parameters used to test general CT use are applicable for lung cancer screening. The technical parameters of the CT subsystem for the Symbia SPECT/CT's and the commercially available SOMATOM standalone CT systems devices with the additional lung cancer screening indication (K142955) were compared, and no differences exist in the parameters. Included in this evaluation, are the following parameters:

- CT number accuracy
- CT number uniformity
- Spatial resolution (MTF, maximum in-plane resolution)
- Slice thickness/sensitivity profile (minimum slice width)
- Noise properties (NPS and image Noise (standard deviation))
- Contrast to Noise Ratio
- Maximum scan speed
- Minimum reconstructed slice interval

The test results demonstrate that the subject devices perform the same as the standalone SOMATOM CT systems. Since the standalone systems have been identified as suitable for lung cancer screening (K142955), the use of the CT component of the Symbia SPECT/CT systems is likewise suitable for lung cancer screening.

Statement regarding Substantial Equivalence:

The Symbia T16, Symbia Intevo 16 and Symbia Intevo Bold SPECT/CT systems are commercially available and no changes to technological, functional or clinical features have been made. There is no difference in the intended use of the device. The CT systems being referenced as predicate devices (K142955) are integrated into the SPECT/CT systems as a subsystem of the device and no differences in functionality have been made compared to the commercially available systems (with the exception of the removal of the tilt functionality). All parameters associated with low dose lung cancer screening are the same between the devices subject to this application and the predicate devices referenced.

Based on the information provided in the Premarket Notification, Siemens Medical Solutions USA, Inc. considers the Symbia T16, Symbia Intevo 16 and Symbia Intevo Bold SPECT/CT systems with the added low dose lung cancer screening indication to be substantially equivalent to the currently commercially available predicate device.