



December 22, 2022

Siemens Medical Solutions USA, Inc.  
% Alaine Medio  
Regulatory Affairs Professional  
810 Innovation Drive  
Knoxville, Tennessee 37932

Re: K223547

Trade/Device Name: Biograph Vision Quadra PET/CT System  
Regulation Number: 21 CFR 892.1200  
Regulation Name: Emission Computed Tomography System  
Regulatory Class: Class II  
Product Code: KPS, JAK  
Dated: November 22, 2022  
Received: November 25, 2022

Dear Alaine Medio:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue watermark of the letters 'FDA'.

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

## Indications for Use

510(k) Number (if known)  
K223547

Device Name  
Biograph Vision Quadra PET/CT System

### Indications for Use (Describe)

The Siemens Biograph Vision Quadra systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.

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 PET subsystem images and measures the distribution of PET radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for the fused PET and CT images.

The system maintains independent functionality of the CT and PET devices, allowing for single modality CT and / or PET diagnostic imaging. These systems are intended to be utilized by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and re staging 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.

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.

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**510(k) Summary**

as required by 21 CFR Part 807.87(h)

**Identification of the Submitter**

Submitter: Alaine Medio  
Regulatory Affairs  
Siemens Medical Solutions USA, Inc.  
Molecular Imaging  
810 Innovation Drive  
Knoxville, TN 37932

Alternative Contact: Tabitha Estes  
Regulatory Affairs

Manufacturer: Siemens Medical Solutions USA, Inc.  
Molecular Imaging  
2501 North Barrington Road  
Hoffman Estates, IL 60192

Telephone Number: (865)206-0337

Fax Number: (865)218-3019

Date of Submission: November 22, 2022

**Identification of the product**

Device Proprietary Name: Biograph Vision Quadra PET/CT System

Common Name: Positron Emission Tomography (PET) 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

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Marketed Devices to which Equivalence is claimed

Primary Predicate

Device:

Device Proprietary Name: Biograph Vision Quadra PET/CT System

Manufacturer: Siemens Medical Solutions USA, Inc.

Product Code: KPS and JAK

Device Class: Class II

510(k) Number: K210262

Reference Devices:

Device Name and 510(k) numbers: Biograph Vision and mCT PET/CT System

Manufacturer: Siemens Medical Solutions USA, Inc.

Product Code: KPS and JAK

Device Class: Class II

510(k) Number: K193248

**Device Description:**

The Biograph Vision Quadra PET/CT system is a combined multi-slice X-Ray Computed Tomography and Positron Emission Tomography scanner. This system is designed for whole body oncology, neurology and cardiology examinations. The Biograph Vision Quadra system provides registration and fusion of high-resolution metabolic and anatomic information from the two major components of each system (PET and CT). Additional components of the system include a patient handling system and acquisition and processing workstations with associated software.

Biograph Vision Quadra software is a command-based program used for patient management, data management, scan control, image reconstruction and image archival and evaluation. All images conform to DICOM imaging format requirements.

The Biograph Vision Quadra is an extended Field of View scanner based on the Biograph Vision 600 Edge scanner. The system incorporates the same CT on the Biograph Vision 600

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Edge but incorporates a 106 cm axial PET FoV. The gantry mechanical frame has been updated to support four (4) times the detectors available on the Biograph Vision 600 systems.

The software for the Biograph Vision Quadra PET/CT system, which is the subject of this application, is substantially equivalent to the commercially available Biograph Vision Quadra software (K210262). Modifications have been made to the commercially available Biograph Vision Quadra software to provide for additional features that are already commercially available in the reference device Biograph Vision software (K193248). These include the following features:

- Gated List Mode (HD Chest)
- Simultaneous Mode
- Continuous Bed Motion
- Shuttle Mode PET Acquisition
- FlowMotion AI (PET FAST Planning)
- FlowMotion MultiParametric PET AI
- OncoFreeze Motion Correction
- OncoFreeze AI
- Quality Guard

Additionally, the following new features have been implemented into the updated Software:

- PET SMART Image Framer (workflow improvement to focus on specific body area) - PET Reconstruction
- Ultra-High Sensitivity Reconstruction - PET Reconstruction

**Intended Use:**

The Siemens Biograph Vision Quadra systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.

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 PET subsystem images and measures the distribution of PET radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for the fused PET and CT images.

The system maintains independent functionality of the CT and PET devices, allowing for single modality CT and / or PET diagnostic imaging.

These systems are intended to be utilized 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.

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 is no change to the Biograph Vision Quadra Intended Use / Indications for use.

**Performance Testing / Safety and Effectiveness:**

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.

PET Testing in accordance with NEMA NU2-2018 was conducted on the Biograph Vision Quadra system.

**Table 1 PET NEMA 2018 Performance Summary Biograph Vision Quadra with a Maximum Ring Difference (MRD) of 85.**

Performance Criteria	Results	Acceptance
<b>Resolution – Full Size</b>		
Transverse Resolution FWHM @ 1 cm	Pass	≤ 4.0 mm
Transverse Resolution FWHM @ 10 cm	Pass	≤ 4.8 mm
Transverse Resolution FWHM @ 20 cm	Pass	≤ 5.2 mm
Axial Resolution FWHM @ 1 cm	Pass	≤ 4.3 mm
Axial Resolution FWHM @ 10 cm	Pass	≤ 5.4 mm
Axial Resolution FWHM @ 20 cm	Pass	≤ 5.4 mm
<b>Sensitivity</b>		
Sensitivity @435 keV LLD	Pass	≥ 70 cps/kBq
Count Rate peak NECR	Pass	≥1200 kcps @ ≤ 36 kBq/cc
Count Rate peak trues	Pass	≥3400 kcps @ ≤ 36 kBq/cc
Scatter Fraction at peak NECR	Pass	≤43%
Mean bias (%) at NEC of 1060 kcps	Pass	[-12,12]
Co-Registration Accuracy	Pass	≤ 5 mm
Time of Flight Resolution at 5.3kBq/cc	Pass	≤249 ps

Performance Criteria	Results	Acceptance
10mm sphere (Contrast / Background Variability)	Pass	≥ 55.0% / ≤ 10.0%
13mm sphere (Contrast / Background Variability)	Pass	≥ 60.0% / ≤ 9.0%
17mm sphere (Contrast / Background Variability)	Pass	≥ 65.0% / ≤ 8.0%
22mm sphere (Contrast / Background Variability)	Pass	≥ 70.0% / ≤ 7.0%
28mm sphere (Contrast / Background Variability)	Pass	≥ 75.0% / ≤ 6.0%
37mm sphere (Contrast / Background Variability)	Pass	≥ 80.0% / ≤ 5.0%
Lung Residual Error	Pass	≤ 5.0%

**Table 2 PET NEMA 2018 Performance Summary Biograph Vision Quadra with a Maximum Ring Difference (MRD) of 322**

Performance Criteria	Results	Acceptance
<b>Resolution – Full Size</b>		
Transverse Resolution FWHM @ 1 cm	Pass	≤ 4.0 mm
Transverse Resolution FWHM @ 10 cm	Pass	≤ 4.8 mm
Transverse Resolution FWHM @ 20 cm	Pass	≤ 5.2 mm
Axial Resolution FWHM @ 1 cm	Pass	≤ 4.3 mm
Axial Resolution FWHM @ 10 cm	Pass	≤ 5.4 mm
Axial Resolution FWHM @ 20 cm	Pass	≤ 5.4 mm
<b>Sensitivity</b>		
Sensitivity @435 keV LLD	Pass	≥ 150 cps/kBq
Count Rate peak NECR	Pass	≥2200 kcps @ ≤ 36 kBq/cc
Count Rate peak trues	Pass	≥6600 kcps @ ≤ 36 kBq/cc
Scatter Fraction at peak NECR	Pass	≤43%
Mean bias (%) at peak NEC	Pass	[-12,12]
Co-Registration Accuracy	Pass	≤ 5 mm
Time of Flight Resolution at 5.3kBq/cc	Pass	≤249 ps
<b>Resolution – Small Size</b>		
10mm sphere (Contrast / Background Variability)	Pass	≥ 55.0% / ≤ 10.0%
13mm sphere (Contrast / Background Variability)	Pass	≥ 60.0% / ≤ 9.0%
17mm sphere (Contrast / Background Variability)	Pass	≥ 65.0% / ≤ 8.0%
22mm sphere (Contrast / Background Variability)	Pass	≥ 70.0% / ≤ 7.0%
28mm sphere (Contrast / Background Variability)	Pass	≥ 75.0% / ≤ 6.0%
37mm sphere (Contrast / Background Variability)	Pass	≥ 80.0% / ≤ 5.0%
Lung Residual Error	Pass	≤ 5.0%

All Performance testing met the predetermined acceptance values.

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



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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 Biograph Vision Quadra system:

- IEC 60601-1: 2005+ A1:2012
- IEC 60601-1-2: 2014
- IEC 60601-1-3: 2013
- IEC 60601-1-6:2010 +A1:2013
- IEC 60601-2-28:2017
- IEC 60601-2-44: 2016
- IEC 60825-1: 2014
- IEC 62366-1: 2015
- ISO 10993-1: 2018
- IEC 61223-2-6:2006
- IEC 61223-3-5:2019
- NEMA XR 25: 2019
- NEMA XR 26: 2012
- NEMA XR 29: 2013
- NEMA PS3.1-3.20
- UL 94: 2013

Additionally, the Biograph Vision Quadra system has been developed in accordance with the requirements of the following standards:

- ISO 13485:2016
- IEC 62304:2015
- ISO 14971:2019

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

Cybersecurity information in accordance with FDA Guidance documents issued October 2, 2014 has been provided. The Biograph Vision Quadra 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 Biograph Vision Quadra and external devices.

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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:**

There have been no changes implemented in the modifications to the Biograph Vision Quadra system that impacts either the fundamental technology or the indications for use. The Biograph Vision Quadra PET/CT system outlined in this Premarket Notification is substantially equivalent to the currently commercially available predicate device.