July 13, 2023

Siemens Medical Solutions USA, Inc.
% Alaine Medio
Regulatory Affairs Manager
2501 N. Barrington Road
HOFFMAN ESTATES IL 60192

Re: K231833
Trade/Device Name: Biograph Vision.X and Biograph Vision.X Edge
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: June 21, 2023
Received: June 22, 2023

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231833

Device Name
Biograph Vision.X and Biograph Vision.X Edge

Indications for Use *(Describe)*
The Siemens Biograph systems are combined x-ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of 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 healthcare 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.

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

K231833

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter:	Alaine Medio Regulatory Affairs Manager Siemens Medical Solutions USA, Inc. Molecular Imaging 810 Innovation Drive Knoxville, TN 37932
Alternative Contact:	Clayton Ginn 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:	June 21, 2023

Identification of the product

Device Proprietary Name:	Biograph Vision.X and Biograph Vision.X Edge
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

Marketed Devices to which Equivalence is claimed

Primary Predicate Device:

Device Proprietary Name:	Biograph Vision PET/CT system
Manufacturer:	Siemens Medical Solutions USA, Inc.
Product Code:	KPS and JAK
Device Class:	Class II
510(k) Number:	K193248

Reference Devices:

Device Name and 510(k) numbers:	SOMATOM Definition AS and Definition Edge CT System
Manufacturer:	Siemens Medical Solutions USA, Inc.
Product Code:	JAK
Device Class:	Class II
510(k) Number:	K190578

Device Description:

The Biograph Vision.X and Biograph Vision.X Edge PET/CT systems are combined multi-slice X-Ray Computed Tomography and Positron Emission Tomography scanners. This system is designed for whole body oncology, neurology and cardiology examinations. The Biograph Vision.X and Biograph Vision.X Edge PET/CT systems provide 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.X and Biograph Vision.X Edge 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.X and Biograph Vision.X Edge scanners are based on the Biograph Vision 600 and Biograph Vision 600 Edge scanners. The primary difference between the

Bigoraph Vision 600 / Vision 600 Edge and Biograph Vision.X / Vision.X Edge scanners is an update to the PET detector electronics assembly (DEA) to provide for better NEMA Time of Flight Resolution.

The software for the Biograph Vision.X and Biograph Vision.X Edge PET/CT system, which is the subject of this application, is substantially equivalent to the commercially available Biograph Vision 600 / Vision 600 Edge software (K193248). Modifications have been made to the commercially available Biograph Vision software to provide for the additional two Biograph Vision configurations. All features and functionality of the Biograph Vision.X and Biograph Vision.X Edge scanners are the same as the commercially available Biograph Vision 600 and Biograph Vision 600 Edge PET/CT scanners (K193248).

Intended Use:

The Siemens Biograph 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.X / Biograph Vision.X Edge systems Intended Use / Indications for use as compared to the Biograph Vision PET/CT Scanners.

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
Resolution – Full Size		
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
Sensitivity @435 keV LLD	Pass	≥ 15 cps/kBq
Count Rate peak NECR	Pass	≥ 250 kcps @ ≤ 36 kBq/cc
Count Rate peak trues	Pass	≥ 1100 kcps @ ≤ 36 kBq/cc
Scatter Fraction at peak NECR	Pass	≤43%
Co-Registration Accuracy	Pass	≤ 5 mm
Time of Flight Resolution at 5.3kBq/cc	Pass	≤ 214 ps
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 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.X and Biograph Vision.X Edge PET/CT Systems:

- IEC 60601-1: 2005+ A1:2012 -- [Rec #19-4]
- IEC 60601-1-2: 2014 – [Rec #19-8]
- IEC 60601-1-3: 2008 + A1:2013 – [Rec # 12-269]
- IEC 60601-1-6:2010 +A1:2013 + A2:2020 – [Rec # 5-132]
- IEC 60601-2-28:2017 – [Rec # 12-309]
- IEC 60601-2-44: 2016 – [Rec # 12-302]
- IEC 60825-1: 2007 – [Rec # 12-273]
- IEC 62366-1: 2015 +A1:2020 – [Rec # 5-129]
- ISO 10993-1: 2018 – [Rec # 2-258]
- IEC 61223-2-6:2006 – [Rec # 12-226]
- IEC 61223-3-5:2019 – [Rec # 12-328]
- NEMA NU 2: 2018 – [Rec # 12-326]
- NEMA XR 25: 2019 – [Rec #12-325]
- NEMA PS3.1-3.20 2021e – [Rec # 12-342]

Additionally, the Biograph Vision,X and Biograph Vision.X Edge systems have been developed in accordance with the requirements of the following standards:

- IEC 62304:2015 – [Rec # 13-79]
- ISO 14971:2019 – [Rec # 5-125]
- ISO 13485:2015

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 has been provided. The Biograph Vision.X and Biograph Vision.X Edge 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.X and Biograph Vision.X Edge 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.

Statement regarding Substantial Equivalence:

There have been no changes implemented in the modifications to the Biograph Vision.X and Biograph Vision.X Edge system that impacts either the fundamental technology or the indications for use as compared to the predicate. The Biograph Vision.X and Biograph Vision.X Edge PET/CT systems outlined in this Premarket Notification are substantially equivalent to the currently commercially available predicate devices (Biograph Vision 600 and Biograph Vision 600 Edge – K193248).