July 3, 2025

Siemens Medical Solutions USA, Inc.
Clayton Ginn
Regulatory Affairs Professional
2501 North Barrington Road
Hoffman Estates, Illinois 60192

Re: K251671
Trade/Device Name: Biograph Vision PET/CT Systems; Biograph mCT PET/CT Systems
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: June 27, 2025
Received: June 27, 2025

Dear Clayton Ginn:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251671

Please provide the device trade name(s).

Biograph Vision PET/CT Systems;
Biograph mCT PET/CT Systems

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary Biograph Vision and Biograph mCT PET/CT Systems

In accordance with 21 CFR §807.92 Content and format of a 510(k) summary.

K251671

1. Identification of the Submitter

Submitter / Primary Contact Person	Clayton Ginn Regulatory Affairs clayton.ginn@siemens-healthineers.com +1 (865) 898-2692
Secondary Contact Person	Alaine Medio Regulatory Affairs Manager alaine.medio@siemens-healthineers.com +1 (865) 206-0337
Applicant Name and Address	Siemens Medical Solutions, Inc. USA 2501 North Barrington Road Hoffman Estates IL, 60192, USA Establishment Registration Number: 1423253

2. Device Name and Classification

Product Trade Name:	Biograph Vision and Biograph mCT PET/CT Systems
Common Name:	Emission computed tomography system (PET) Computed tomography x-ray system (CT)
Classification Name:	System, Tomography, Computed, Emission (PET) System, X-Ray, Tomography, Computed (CT)
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1200
Device Class:	Class II
Product Code:	KPS (PET) and JAK (CT)

3. Predicate Devices

Primary Predicate Device:

Product Trade Name:	Biograph Vision and Biograph mCT PET/CT Systems
510(k) Number	K193248
Clearance Date	02/14/2020
Common Name:	Emission computed tomography system (PET) Computed tomography x-ray system (CT)
Classification Name:	System, Tomography, Computed, Emission (PET) System, X-Ray, Tomography, Computed (CT)
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1200
Device Class:	Class II
Product Code:	KPS (PET) and subsequent product code JAK (CT)

Reference Devices:

1)

Product Trade Name:	Biograph Vision.X and Biograph Vision.X Edge
510(k) Number	K231833
Clearance Date	07/13/2023
Common Name:	Emission computed tomography system (PET) Computed tomography x-ray system (CT)
Classification Name:	System, Tomography, Computed, Emission (PET) System, X-Ray, Tomography, Computed (CT)
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1200
Device Class:	Class II
Product Code:	KPS (PET) and subsequent product code JAK (CT)

2)

Product Trade Name:	Biograph Vision Quadra PET/CT System
510(k) Number	K223547
Clearance Date	12/22/2022
Common Name:	Emission computed tomography system (PET) Computed tomography x-ray system (CT)
Classification Name:	System, Tomography, Computed, Emission (PET) System, X-Ray, Tomography, Computed (CT)
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1200
Device Class:	Class II
Product Code:	KPS (PET) and subsequent product code JAK (CT)

3)

Product Trade Name:	SOMATOM Definition Edge, SOMATOM Definition AS/AS+
510(k) Number	K230421
Clearance Date	06/16/2023
Common Name:	Computed tomography x-ray system
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

4. Device Description

The Biograph Vision and Biograph mCT PET/CT systems are combined multi-slice X-Ray Computed Tomography and Positron Emission Tomography scanners. These systems are designed for whole-body oncology, neurology and cardiology examinations. The Biograph Vision and Biograph mCT 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 and Biograph mCT 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 software for the Biograph Vision and Biograph mCT systems, which are the subject of this application, is substantially equivalent to the commercially available Biograph Vision and Biograph mCT software.

- Somaris Software (cleared in K230421)
    - Upgrade to the latest revision of Somaris Software (Somaris/7 syngo CT VB30) with modified software features:
        - FAST Bolus
        - FAST 4D
        - FAST Applications (FAST Spine, FAST Planning)
        - Automatic Patient Instructions
        - Additional default exam protocols
        - Additional kV setting for Tin Filtration
- PETsyngo software
    - SMART Image Framer (available for Vision 600 and X models only – cleared in K223547)
- Updated computer hardware due to obsolescence issues (cleared in K230421). These changes do not affect system performance characteristics and have no impact on safety or effectiveness.

The Biograph Vision may also use the names Biograph Vision Quantum and Peak for marketing purposes.

5. Indications for 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.

6. Indications for Use Comparison to the Predicate Device

The indications for use are the same between the subject device and the primary predicate device.

7. Technological Comparison

Biograph Vision and Biograph mCT PET/CT Systems with software version VG85 provide the same technological characteristics in terms of design, materials, chemical composition, energy source, and control mechanisms when compared to the legally marketed predicate devices Biograph Vision and Biograph mCT Systems with software version VG80.

The intended use, indications for use, and fundamental scientific technology for the subject device remain unchanged from the predicate device. No features present from the predicate device have been de-scoped. The software features have been modified in comparison to the predicate device to support enhanced device functionality and computer hardware has been updated due to obsolescence issues.

Differences in technological characteristics described in section 4 above (software feature updates for scanning and reconstruction and computer hardware updates) do not raise different questions of safety and effectiveness as they are cleared in the primary and reference predicate devices. Testing and validation are completed. Test results show that the subject devices are comparable to the predicate devices in terms of technological characteristics, safety, and effectiveness and therefore, are substantially equivalent to the predicate devices.

8. Non-Clinical and/or Clinical Test Summary & Conclusions

Non-Clinical Testing

Performance testing for the CT subsystem was included in the original premarket notification for the CT subsystems, and there have been no changes to this testing.

PET Testing in accordance with NEMA NU2-2018 was conducted on the Biograph Vision and Biograph mCT systems. All Performance testing met the predetermined acceptance values.

Performance Criteria Resolution – Full Size	Results	Subject Device: Biograph Vision and Biograph mCT (VG85)	Predicate: Biograph Vision Biograph mCT (K193248)
Transverse Resolution FWHM @ 1 cm	Pass	Same	≤ 4.0 mm (Vision) ≤ 4.7 mm (mCT)
Transverse Resolution FWHM @ 10 cm	Pass	Same	≤ 4.8 mm (Vision) ≤ 5.4 mm (mCT)
Transverse Resolution FWHM @ 20 cm	Pass	Same	≤ 5.2 mm (Vision) ≤ 6.3 mm (mCT)
Axial Resolution FWHM @ 1 cm	Pass	Same	≤ 4.3 mm (Vision) ≤ 4.9 mm (mCT)
Axial Resolution FWHM @ 10 cm	Pass	Same	≤ 5.4 mm (Vision) ≤ 6.5 mm (mCT)
Axial Resolution FWHM @ 20 cm	Pass	Same	≤ 5.4 mm (Vision) ≤ 8.8 mm (mCT)
Count Rate / Scatter / Sensitivity			
Sensitivity @435 keV LLD	Pass	Same	≥ 8.0 cps/kBq (Vision 450) ≥ 15.0 cps/kBq (Vision 600) ≥ 5.0 cps/kBq – (mCT 3R) ≥ 9.4 cps/kBq – (mCT 4R)
Count Rate peak NECR	Pass	Same	≥140 kcps @ ≤ 32 kBq/cc (Vision 450) ≥250 kcps @ ≤ 32 kBq/cc (Vision 600 and X) ≥95 kcps @ ≤ 30 kBq/cc (mCT 3R) ≥165 kcps @ ≤ 40 kBq/cc (mCT 4R)
Count Rate peak trues	Pass	Same	≥600 kcps @ ≤ 56 kBq/cc (Vision 450) ≥1100 kcps @ ≤ 56 kBq/cc (Vision 600 and X) ≥350 kcps @ ≤ 46 kBq/cc (mCT 3R) ≥575 kcps @ ≤ 40 kBq/cc (mCT 4R)
Scatter Fraction (435 keV LLD)	Pass	Same	≤43% @ Peak *≤40% @ low activity (Vision) ≤40% @ Peak *≤37% @ low activity (mCT)

Performance Criteria Resolution – Full Size	Results	Subject Device: Biograph Vision and Biograph mCT (VG85)	Predicate: Biograph Vision Biograph mCT (K193248)
Co-Registration Accuracy	Pass	Same	≤ 5 mm
Time of Flight Resolution at 5.3kBq/cc	Pass	Same	≤ 214 ps (Vision.X) ≤ 249 (Vision 450 and 600) ≤600 (mCT)
Mean bias [%] at peak NEC	Pass	Same	[-6, 6]
Image Quality – (% Contrast / Background Variability)			
10mm sphere	Pass	Same	≥ 55% / ≤ 10% (Vision) ≥ 10% / ≤ 10% (mCT)
13mm sphere	Pass	Same	≥ 60% / ≤ 9% (Vision) ≥ 25% / ≤ 10% (mCT)
17mm sphere	Pass	Same	≥ 65% / ≤ 8% (Vision) ≥ 40% / ≤ 10% (mCT)
22mm sphere	Pass	Same	≥ 70% / ≤ 7% (Vision) ≥ 55% / ≤ 10% (mCT)
28mm sphere	Pass	Same	≥ 75% / ≤ 6% (Vision) ≥ 60% / ≤ 10% (mCT)
37mm sphere	Pass	Same	≥ 80% / ≤ 5% (Vision) ≥ 65% / ≤ 10% (mCT)

Verification and validation testing substantiates and is traceable to all requirement and functional specifications, including specifications related to device hazards, and supports the claim of substantial equivalence.

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.

Clinical Testing

Clinical testing was not conducted for this submission.

Conclusion

There are no differences in the Indications for Use, Intended Use, or Fundamental Technological Characteristics of the Biograph Vision and Biograph mCT VG85 software as compared to the currently commercially available Biograph Vision (including Vision.X - K231833) and Biograph mCT software (K193248).

The new features implemented within this release do not raise any new issues of safety and effectiveness as compared to the predicate device. The predicate devices were cleared based on the

results of non-clinical testing, which included verification and validation, phantom tests, and supportive literature. The subject device is also validated using the same methods as used for the predicate devices. The non-clinical verification and validation demonstrate that the subject devices should perform as intended in the specified use conditions.

The Biograph Vision and Biograph mCT systems, with the modifications outlined in this Premarket Notification, are substantially equivalent to the commercially available predicate device.