January 15, 2026

Siemens Healthineers AG
℅ Alina Goodman
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, Pennsylvania 19355

Re: K253023
Trade/Device Name: BIOGRAPH One
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: OUO, KPS, LNH, LNI, MOS
Dated: September 19, 2025
Received: December 8, 2025

Dear Alina Goodman:

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, PhD
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253023

Device Name
BIOGRAPH One

Indications for Use *(Describe)*

Magnetic Resonance Imaging (MRI) is a noninvasive technique used for diagnostic imaging. MRI with its soft tissue contrast capability enables the healthcare professional to differentiate between various soft tissues, for example, fat, water, and muscle, but can also visualize bone structures.

Depending on the region of interest, contrast agents may be used.

The MR system may also be used for imaging during interventional procedures and radiation therapy planning.

The PET images and measures the distribution of PET radiopharmaceuticals in humans to aid the physician in determining various metabolic (molecular) and physiologic functions within the human body for evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders, and cancer.

The integrated system utilizes the MRI for radiation-free attenuation correction maps for PET studies. The integrated system provides inherent anatomical reference for the fused MR and PET images due to precisely aligned MR and PET image coordinate systems.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR § 807.92.

1. General Information

Establishment:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared: September 19, 2025

Manufacturer:
Siemens Healthineers AG
Magnetic Resonance (MR)
Allee am Röthelheimpark 2
91052 Erlangen
Germany
Registration Number: 3002808157

Siemens Shenzhen Magnetic Resonance LTD.
Siemens MRI Center
Hi-Tech Industrial Park (middle)
Gaoxin C. Ave., 2nd
Shenzhen 518057
P.R. CHINA
Registration Number: 3004754211

2. Contact Information

Alina Goodman
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Phone: +1(317)371-8593
E-mail: alina.goodman@siemens-healthineers.com

3. Device Name and Classification

Device/ Trade name: BIOGRAPH One
Classification Name: Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance
Classification Panel: Radiology
CFR Code: 21 CFR § 892.1200
21 CFR § 892.1000

Classification:	II
Product Code:	Primary: OUO Secondary: KPS, LNH, LNI, MOS

4. Legally Marketed Predicate and Reference Device

4.1. Predicate Device

Trade name:	Biograph mMR
510(k) Number:	K200213
Classification Name:	Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1200 21 CFR § 892.1000
Classification:	II
Product Code:	Primary: OUO Secondary: KPS, LNH, LNI, MOS

4.2. Reference Device

Trade name:	MAGNETOM Vida
510(k) Number:	K231560
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

Trade name:	MAGNETOM Cima.X
510(k) Number:	K231587
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

Device/ Trade name:	MAGNETOM Sola
510(k) Number:	K232535
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

Trade name:	Biograph Vision PET/CT
510(k) Number:	K251671
Classification Name:	System, Tomography, Computed, Emission

Classification Panel:	Radiology
CFR Code:	21 CFR §892.1200
Classification:	II
Product Code:	Primary: KPS Secondary: JAK

Trade name:	Biograph Trinion
510(k) Number:	K251561
Classification Name:	System, Tomography, Computed, Emission
Classification Panel:	Radiology
CFR Code:	21 CFR 892.1200 21 CFR 892.1750
Classification:	II
Product Code:	Primary: KPS Secondary: JAK

Trade name:	MAGNETOM Free.Max
510(k) Number:	K231617
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: MOS

Trade name:	MAGNETOM Flow.Ace
510(k) Number:	K250436
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

Trade name:	MAGNETOM Sola Fit
510(k) Number:	K250443
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

Trade name:	MAGNETOM Skyra Fit
510(k) Number:	K250443
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II

Product Code: Primary: LNH
Secondary: LNI, MOS

Trade name: syngo.via VB40A
510(k) Number: K191040
Product Code: Primary: LLZ

5. Intended Use / Indications for Use

The indications for use for the subject device have been updated compared to the predicate device to fit EU and FDA regulations and have been improved in the wording:

Indications for Use:
Magnetic Resonance Imaging (MRI) is a noninvasive technique used for diagnostic imaging. MRI with its soft tissue contrast capability enables the healthcare professional to differentiate between various soft tissues, for example, fat, water, and muscle, but can also visualize bone structures.

Depending on the region of interest, contrast agents may be used.

The MR system may also be used for imaging during interventional procedures and radiation therapy planning.

The PET images and measures the distribution of PET radiopharmaceuticals in humans to aid the physician in determining various metabolic (molecular) and physiologic functions within the human body for evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders, and cancer.

The integrated system utilizes the MRI for radiation-free attenuation correction maps for PET studies. The integrated system provides inherent anatomical reference for the fused MR and PET images due to precisely aligned MR and PET image coordinate systems.

6. Device Description

BIOGRAPH One with software Syngo MR XB10 includes new and modified hardware and software compared to the predicate device, Biograph mMR with software syngo MR E11P-AP01. A high level summary of the new and modified hardware and software is provided below:

Hardware

New Hardware

- Gantry offset phantom
- SDB (Smart Distribution Box)

New Coils

- BM Contour XL Coil
- BM Head/Neck Pro PET-MR Coil
- BM Spine Pro PET-MR Coil
- Transfer of up-to-date RF coils from the reference device MAGNETOM Vida.

Modified Hardware

- Main components such as:
  - Detector cassettes / DEA
  - Phantom holder
  - Gantry tube
  - Backplane
  - Magnet and cabling
  - Gradient coil
  - MaRS (measurement and reconstruction system)
  - MI MARS
  - PET electronics
  - RF transmitter TBX3 3T (TX Box 3)
- Other components such as:
  - Cover
  - Filter plate
  - Patient table
  - RFCEL_TEMP

Modified Coils

- Body coil
- Transfer of up-to-date RF coils from the reference device MAGNETOM Vida with some improvements.

Software

New Features and Applications

- Fast Whole-Body workflows
- Fast Head workflow
- myExam PET-MR Assist
- CS-Vibe
- myExam Implant Suite
- DANTE blood suppression
- SMS Averaging for TSE
- SMS Averaging for TSE_DIXON
- SMS without diffusion function
- BioMatrix Motion Sensor
- RF pulse optimization with VERSE
- Deep Resolve Boost for FL3D_VIBE and SPACE
- Deep Resolve Sharp for FL3D_VIBE and SPACE
- Preview functionality for Deep Resolve Boost
- EP2D_FID_PHS
- EP_SEG_FID_PHS
- ASNR recommended protocols for imaging of ARIA
- Open Workflow
- Ultra HD-PET
- “MTC Mode”
- OpenRecon 2.0
- Deep Resolve Boost for TSE
- GRE_PC
- The following functions have been migrated for the subject device without modifications from MAGNETOM Skyra Fit and MAGNETOM Sola Fit:
  - 3D Whole Heart

  - Ghost reduction (Dual polarity Grappa (DPG))
  - Fleet Reference Scan
  - AutoMate Cardiac (Cardiac AI Scan Companion)
  - Complex Averaging
  - SPACE Improvement: high bandwidth IR pulse
  - SPACE Improvement: increase gradient spoiling
- The following function has been migrated for the subject device without modifications from MAGNETOM Free.Max:
  - myExam Autopilot Spine
- The following functions have been migrated for the subject device without modifications from MAGNETOM Sola:
  - myExam Autopilot Brain
  - myExam Autopilot Knee
- Transfer of further up-to-date SW functions from the reference devices.

New Software / Platform
- PET-Compatible Coil Setup
- Select&GO
- PET-MR components communication

Modified Features and Applications
- HASTE_CT
- FL3D_VIBE_AC
- PET Reconstruction
- Transfer of further up-to-date SW functions from the reference devices with some improvements.

Modified Software / Platform
- Several software functions have been improved. Which are:
  - PET Group
  - PET Viewing
  - PET RetroRecon
  - PET Status and Tune-up/QA

Other Modifications and / or Minor Changes
- Indications for use
- Contraindications
- SAR parameter
- Off-Center Planning Support
- Flip Angle Optimization (Lock TR and FA)
- Inline Image Filter
- Marketing bundle “myExam Companion”
- ID Gain
- Automatic System Shutdown (ASS) sensor (Smoke Detector)
- Patient data display (PDD)

7. Substantial Equivalence

BIOGRAPH One with software Syngo MR XB10 is substantially equivalent to the following device:

Predicate Devices	FDA Clearance Number and Date	Product Code	Manufacturer

Biograph mMR with syngo MR E11P-AP01	K200213, cleared on May 11, 2020	OUO LNH, LNI, KPS	Siemens Healthcare GmbH

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with syngo MR XA60A	K231560, cleared on October 23, 2023	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Cima.X with syngo MR XA61A	K231587, cleared on December 18, 2023	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Sola with syngo MR XA61A	K232535, cleared on December 22, 2023	LNH, LNI, MOS	Siemens Healthcare GmbH
Biograph Vision PET/CT with PETsyngo VG85A	K251671, cleared on July 3, 2025	KPS, JAK	Siemens Medical Solutions, Inc. USA
Biograph Trinion with PETsyngo VK20	K251561, cleared on July 31, 2025	KPS, JAK	Siemens Medical Solutions, Inc. USA
MAGNETOM Free.Max with syngo MR XA60A	K231617, cleared on September 11, 2023	LNH, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Flow.Ace with syngo MR XA70A	K250436, cleared on June 16, 2024	LNH, LNI, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Sola Fit with syngo MR XA70A	K250443, cleared on June 16, 2024	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Skyra Fit with syngo MR XA70A	K250443, cleared on June 16, 2024	LNH, LNI, MOS	Siemens Healthcare GmbH
syngo.via VB40A	K191040, cleared on May 16, 2019	LLZ	Siemens Healthcare GmbH

8. Technological Characteristics

The subject device, BIOGRAPH One with software Syngo MR XB10, is substantially equivalent to the predicate device with regard to the operational environment, programming language, operating system and performance.

The subject devices conform to the standard for medical device software (IEC 62304) and other relevant IEC and NEMA standards.

While there are some differences in technological characteristics between the subject devices and predicate device based on hardware and software modifications to fit to this PET-MR system combination specific needs and to represent state-of-the-art technology with up-to-dated hardware and software as well as new and modified hardware and software in general, these differences have been tested and the conclusions from the nonclinical data suggest that the features bear an equivalent safety and performance profile to that of the predicate device.

9. Nonclinical Tests

The following performance testing was conducted on the subject devices:

Performance Test	Tested Hardware or Software	Source/Rationale for test
Software verification and validation	New or modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Sample clinical images	Coils, new or modified software features	Guidance for submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Image quality assessment by sample clinical images	- new / modified pulse sequence types. - comparison images between the new / modified features and the predicate device features	
Performance bench test	New and modified hardware	
Biocompatibility	surface of applied parts	ISO 10993-1
Electrical, mechanical, structural, and related system safety test	complete system	- AAMI / ANSI ES60601-1 - IEC 60601-2-33
Electrical safety and electromagnetic compatibility (EMC)	Complete system	IEC 60601-1-2

The results from each set of tests demonstrate that the subject devices perform as intended and are thus substantially equivalent to the predicate device to which it has been compared.

Below table shows an executive summary of training and validation dataset of new AI features in the subject devices.

Deep Resolve Boost for FL3D_VIBE and Deep Resolve Boost for SPACE:

Test result summary	Quantitative evaluations of structural similarity index (SSIM), peak signal-to-noise ratio (PSNR) and mean squared error (MSE) metrics showed a convergence of the training and

	improvements compared to conventional parallel imaging. An inspection of the test images did not reveal any negative impact to the image quality. The function has been used either to acquire images faster or to improve image quality.
Test setup	Equipment: 0.55T, 1.5T and 3T scanners Protocols: representative measurement protocols (T1, T2 and PD with and without fat saturation) which have been altered for training (e.g. to increase SNR, increase resolution or reduce acceleration). Body regions: broad range of body regions Used coils: broad range of coils to cover the dedicated body regions
	Sample size: 27,679 3D patches from 1265 measurements
	Dataset split: Training: 81% of the 1265 measurements Validation: 19% of the 1265 measurements Note: Data split maintained similar data distribution (e.g., contrast, orientation, field strength, …) in both training and validation datasets.
	Sample source: in-house measurements (training and validation) and collaboration partners (testing)
Patient Characteristics	Gender distribution: - Male: 53% - Female 47% Age: for training and validation. - 19 - 45: 14% - 46 - 65: 43% - 66 - 89: 43% Clinical subgroups: No clinical subgroups have been defined for the datasets.
Reference standard	The acquired datasets (as described above) represent the ground truth for the training and validation. Input data was retrospectively created from the ground truth by data manipulation and augmentation. This process includes further undersampling of the data by discarding k-space lines as well as creating sub-volumes of the acquired data.
Data independency	Datasets determined for training and validation were split prior to training along individual acquisitions to ensure that there is no mixture of sub-volumes stemming from the same acquisition.

Deep Resolve Sharp for FL3D_VIBE and Deep Resolve Sharp for SPACE:

Test result summary	The impact of the Deep Resolve Sharp network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR), structural similarity index (SSIM), and perceptual loss. The tests include rating and an evaluation of image sharpness by intensity profile comparisons of reconstruction with and without Deep Resolve Sharp. Both

	tests show increased edge sharpness and reduced Gibb's artifacts.
Test setup	Equipment: 0.55T, 1.5T and 3T MRI scanners Protocols: representative measurement protocols (T1, T2 and PD with and without fat saturation) which have been altered (e.g. to increase SNR, increase resolution or reduce acceleration) Body regions: broad range of different body regions. Used coils: broad range of coils to cover the dedicated body regions
	Sample size: approx. 13,000 high resolution 3D patches from 500 measurements.
	Dataset split: Training: 70% of the 500 measurements. Validation: 30% of the 500 measurements Note: Data split maintained similar data distribution (e.g., contrast, orientation, field strength, …) in both training and validation datasets.
	Sample source: in-house measurements
Patient Characteristics	Gender distribution: - Male: 66.6% - Female 33.4% Age: for training and validation. - 19 - 45: 8.4% - 46 - 65: 40.2% - 66 - 89: 51.4% Clinical subgroups: No clinical subgroups have been defined for the datasets.
Reference standard	The acquired datasets represent the ground truth for the training and validation. Input data was retrospectively created from the ground truth by data manipulation. k-space data has been cropped such that only the center part of the data was used as input. With this method corresponding low-resolution data as input and high-resolution data as output / ground truth were created for training and validation.
Data independency	The high-resolution datasets were split to 70% training and 30% validation datasets before training to ensure independence of them. The input and output variables of the network have been derived from the same dataset so that no confounders exist for the training methodology.

Deep Resolve Boost for TSE:

Test result summary	The evaluation on the test dataset confirmed very similar metrics in terms of peak signal-to-noise ratio (PSNR), structural similarity index (SSIM) and learned perceptual image patch similarity metrics (LPIPS) for the predicate and the modified network with both outperforming conventional GRAPPA as the reference. Visual evaluations confirmed

	statistically significant reduction of banding artifacts with no significant changes in sharpness and detail visibility. In addition, the radiologist evaluation revealed no difference in suitability for clinical diagnostics between updated and cleared predicate network. The function as on the predicate devices was modified to the subject devices but the training and testing from the predicate devices still fits.
Test setup	Equipment: 0.55T, 1.5T and 3T MRI scanners Protocols: representative protocols (T1, T2 and PD with and without fat saturation) Body regions: broad range of different body regions Used coils: broad range of coils to cover the dedicated body regions Testing of the Deep Resolve Boost network has been described in the reference and predicate device submissions. Additional tests have been performed to evaluate the banding artifact reduction capabilities of the updated network.
	Dataset split: Training: more than 23250 slices (93%) Validation: more than 1750 slices (7%) Additional test dataset for banding artifact reduction: more than 2000 slices For training and validation of the network, the identical data was used as for the initial device submission (K213693). Note: Data split maintained similar data distribution (e.g., contrast, orientation, field strength, …) in both training and validation datasets.
	Sample source: in-house measurements and collaboration partners
Patient Characteristics	Due to reasons of data privacy, gender, age and ethnicity during data collection have not been recorded. Due to the network architecture, attributes like gender, age and ethnicity are not relevant to the training data.
	No clinical subgroups have been defined for the collected dataset
Reference standard	The acquired training/validation datasets (identical to the initial submission K213693) represent the ground truth for the training and validation. Input data was retrospectively created from the ground truth by data manipulation and augmentation. This process includes further undersampling of the data by discarding k-space lines, lowering of the SNR level by addition of noise and mirroring of k-space data.
Data independency	Training and validation datasets were kept independent from each other during training and validation. The acquired datasets (one dataset consists of a group of multiple slices) were split into 93% training and 7% validation data prior to the

	training. A similar distribution was maintained for training and validation data. The test dataset for banding artifact reduction was acquired after the release of the predicate network and is therefore independent of the training/validation data.

The results from each set of tests demonstrate that the device performs as intended and is thus substantially equivalent to the predicate device to which it has been compared.

10. Clinical Tests

To provide clinical sample images for some modifications of the subject devices, references to a clinical investigation report are provided as well as, sample clinical images were provided as stated above.

11. Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to ensure 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 of potential hazards early in the design cycle and continuously throughout the development of the product. Siemens Healthcare GmbH adheres to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards. Furthermore, the device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

The subject devices with Syngo MR XB10 conform to the following FDA recognized and international IEC, ISO and NEMA standards:

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
19-46	General II (ES/ EMC)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	ES60601-1:2005 /(R)2012 & A1:2012, C1:2009/(R)2012 &A2:2010/(R)2012 (Cons. Text) [Incl.AMD2:2021]	ANSI AAMI

19-36	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	60601-1-2 Edition 4.1 2020-09	IEC
12-347	Radiology	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	60601-2-33 Edition 4.0 2022-08	IEC
5-125	General I (QS/ RM)	Medical devices - Application of risk management to medical devices	14971 Third edition 2019-12	ISO
5-129	General I (QS/ RM)	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1: 2015 + AMD1:2020	IEC
13-79	Software / Informatics	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	IEC 62304:2006 + AMD1:2015	IEC
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4-2010	NEMA
12-288	Radiology	Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images	MS 9-2008 (R2020)	NEMA
12-352	Radiology	Digital Imaging and Communications in Medicine (DICOM)	PS 3.1 - 3.20 (2023e)	NEMA
2-258	Biocompatibility	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process. (Biocompatibility)	10993-1: 2018	ANSI AAMI ISO
12-382	Radiology	Performance Measurements of Positron Emission Tomographs	NU 2-2024	NEMA

12. Conclusion as to Substantial Equivalence

BIOGRAPH One with software syngo MR XB10A has similar intended use and basic technological characteristics as the predicate device system, Biograph mMR

with software syngo MR E11P-AP01, with respect to the features and functionalities. While there are differences in technical features compared to the predicate devices, the differences have been tested and the conclusions from all verification and validation data suggest that the features bear an equivalent safety and performance profile to that of the predicate device and reference devices.

Siemens believes that the subject device BIOGRAPH One with software Syngo MR XB10 is substantially equivalent to the currently marketed device Biograph mMR with software syngo MR E11P-AP01, which was 510(k) cleared under K200213 on May 11, 2020.