July 31, 2026

Siemens Healthineers AG
% Milind Dhamankar
Clinical Affairs and Regulatory Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Blvd.
Malvern, Pennsylvania 19355

Re: K260852
Trade/Device Name: MAGNETOM Flow.Elite; MAGNETOM Flow.Neo; MAGNETOM Flow.Rise; MAGNETOM Flow.Pure
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: July 7, 2026
Received: July 7, 2026

Dear Milind Dhamankar:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

NINGZHI LI -S

Digitally signed by NINGZHI LI -S

for
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

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)*
K260852

Device Name
MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise, MAGNETOM Flow.Pure.

Indications for Use *(Describe)*

The MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, and that displays, depending on optional local coils that have been configured with the system, the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

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.

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:

July 29, 2026

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
Gaoxin C, Ave. 2nd
Hi-Tech Industrial Park
518057 Shenzhen
Peoples Republic of China
Registration Number: 3004754211

2. Contact Information

Milind Dhamankar, M.D.
Clinical Affairs and Regulatory Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Cell: (610) 517-9484
E-mail: milind.dhamankar@siemens-healthineers.com

3. Device Name and Classification

Device/ Trade name:	MAGNETOM Flow.Elite
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 Flow.Neo
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 Flow.Rise
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 Flow.Pure
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

4. Legally Marketed Predicate Device

Trade name:	MAGNETOM Flow.Elite
510(k) Number:	K252838
Clearance Date:	December 19, 2025
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 Flow.Neo
510(k) Number:	K252838
Clearance Date:	December 19, 2025
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 Flow.Rise
510(k) Number:	K252838
Clearance Date:	December 19, 2025
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

5. Indications for Use

The indications for use for the subject devices is the same as the predicate device:

The MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, and that displays, depending on optional local coils that have been configured with the system, the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

6. Device Description

MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise and MAGNETOM Flow.Pure with software Syngo MR XB20A includes new and modified hardware and software compared to the predicate devices, MAGNETOM Flow.Elite, MAGNETOM Flow.Neo and MAGNETOM Flow.Rise with software Syngo MR XB10A. A high level summary of the new and modified hardware and software is provided below:

Hardware	New Hardware	- BioMatrix Patient Table Vertical Drive Pro and BioMatrix Dockable Table Pro with eDrive - P70 Gradient System - Receive Cabinet Electronic - Tx_Components - local TX path
	New Coils	- BM Spine Pro - BM Head/Neck Pro - BM Contour Pro S - BM Contour Pro M - BM Contour Pro L - Pediatric 16 - TxRx CP Head - Tx/Rx Knee 18
Software	New Features and Applications	- myExam Foot Assist - myExam Ankle Assist - myExam Ankle Autopilot - EP_SEG_FID - BioMatrix Shim - Deep Resolve Boost for TSE_DIXON, SE_17RB130 and SE - myExam Pelvis RT Autopilot - Deep Resolve Boost for TFL / MPRAGE imaging - 3D Whole Heart Pro - myExam Hip Autopilot - myExam Shoulder Autopilot - Deep Resolve Sharp with partial fourier - Deep Resolve Sharp for Cine - Deep Resolve Sharp for TFL / MPRAGE imaging - Inline Perfusion (Slice timing correction) - Brachytherapy Support

	New Software / Platform	- BioMatrix Motion Sensor (Motion Detection) - Shutdown timer - Open Sequence *
	Modified Features and Applications	- AutoAlign - Direct Motion Scan - SE with Flow Compensation Method - FWS for TFL (MPRAGE) - Operator Guidance and Direct Patient Setup for Radiotherapy (RT) - SE and SE_17RB130 with GRAPPA - T2-prep for SPACE - Fat Sat and SPAIR - TR and flip angle codependency - TFL with 3D Acceleration
	Modified Software / Platform	- Select&GO at the PDD / TPAN - Advanced Interactive Realtime - myNeedle Guide MR
Other Modifications and / or Minor Changes		- Renaming RXCEL_S - Renaming “3D WholeHeart”

* Note: The Open Sequence Framework is an infrastructure framework that allows separately FDA-cleared pulse sequence applications - developed by Siemens, or third-party manufacturers - to connect to the MR scanner via a direct network link and operate independently of the scanner's native software version. Pulse sequence applications run on an external device (e.g., a laptop or PC), and image reconstruction is performed on that external device, not on the MR scanner itself. The Open Sequence Framework only permits FDA-cleared pulse sequence applications to be used for clinical purposes. Open Sequence Application manufacturers are responsible for the clinical functionality of their application, including demonstration of diagnostic image quality, safety, and compatibility with the specific MR system(s) and field strength(s) for which clearance was obtained. Use of an Open Sequence Application on a system or field strength other than those for which it was cleared may result in unknown or degraded performance. Siemens is responsible for verifying FDA authorization of any third-party Open Sequence Application prior to enabling its use on the platform. User documentation provided by the third-party manufacturer, including intended use, system compatibility, and applicable constraints, will be made available to the end user at the time of installation.

7. Substantial Equivalence

MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise and MAGNETOM Flow.Pure with software Syngo MR XB20A is substantially equivalent to the following predicate devices:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Flow.Elite, MAGNETOM Flow.Neo and MAGNETOM Flow.Rise with Syngo MR XB10A	K252838, cleared on December 19, 2025	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise and MAGNETOM Flow.Pure with software Syngo MR XB20A includes hardware and software already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Sola with software Syngo MR XB10A	K252838, cleared on December 19, 2025	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Altea with software Syngo MR XB10A	K252838, cleared on December 19, 2025	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Free.Max with syngo MR XA80A	K251822 cleared on November 20, 2025	LNH MOS	Siemens Shenzhen Magnetic Resonance, Ltd.
MAGNETOM Free.Star with syngo MR XA80A	K251822 cleared on November 20, 2025	LNH MOS	Siemens Shenzhen Magnetic Resonance, Ltd.
MAGNETOM Terra.X with syngo MR XA60A	K232322 cleared on March 22, 2024	LNH LNI, MOS	Siemens Healthcare GmbH

8. Comparison of technological Characteristics with the Predicate Device

The subject devices, MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise and MAGNETOM Flow.Pure with software Syngo MR XB20A, are substantially equivalent to the predicate devices 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 devices, including new and modified hardware and software, these differences have been tested and the conclusions from the non-clinical data suggests that the features bear an equivalent safety and performance profile to that of the predicate devices.

9. Nonclinical Tests

The following performance testing was conducted on the subject devices.

Performance Test	Tested Hardware or Software	Source/Rationale for test
Sample clinical images	coils, new and modified hardware and software	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Image quality assessments 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	
Software verification and validation	new and modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
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

AI Features/Applications training and validation:

The information below shows an executive summary of training and validation dataset of the AI features:

AutoAlign extension to Ankle and Foot:

Test result summary	Quantitative evaluations of training and validation error metrics showed a convergence of the training. Inspection of the results on the validation set showed that out of the 1620 references (108 test data sets with each containing 15 foot and ankle AutoAlign references), 45 references required manual adjustment. This indicates an accuracy of 97.2% for the AutoAlign plannings.
Test setup	add equipment and protocols used to collect images Equipment: scanners at different field strength

	Protocols: 3D Localizer images for the foot and ankle were used. Body regions: ankle and foot Used coils: broad range of coils to cover the dedicated body regions
	Sample size: 370 3D localizer images of the foot resp. ankle (262 train, 108 test)
	Dataset split: Training: 71% of the measurements Validation: 29% of the measurements. Data split is patient disjoint. Sample source house: in-measurements (training and validation)
Patient characteristics	Gender distribution for training and validation: - Male: 53% - Female: 47% Age for training and validation: - 19 - 45: 14% - 46 - 65: 43% - 66 - 89: 43%
Reference standard	The ground truth was established through manual annotation of 35 landmarks in 262 training samples by radiologist and in-house trained annotators with MSK expertise. Landmarks were also annotated in the 108 testing samples by in-house trained annotators. The labels in the acquired datasets (as described above) represent the ground truth for the training and validation.
Data independency	Training and testing sets are patient-disjoint, meaning that all images of a given patient were placed in one and only one of the sets

Deep Resolve Sharp for Cine:

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, PD, Cine, Diffusion and Dixon 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. 21963 high resolution 2D slices from 694 measurements.
	Dataset split: Training: 70% of the 694 measurements.

	Validation: 30% of the 694 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: 28.6% - Female 67.1% - Others: 4.3% Age: for training and validation. - 19 - 45: 28.1% - 46 - 65: 41.1% - 66 - 89: 30.8% 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 Sharp with partial fourier:

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. 21963 high resolution 2D slices from 694 measurements.
	Dataset split: Training: 70% of the 694 measurements. Validation: 30% of the 694 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: 28.6% - Female 67.1% - Others: 4.3% Age: for training and validation. - 19 - 45: 28.1% - 46 - 65: 41.1% - 66 - 89: 30.8% 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_DIXON, SE_17RB130 and SE:

Test result summary	The function scope as on the predicate devices was extended to the subject devices but the function has not been modified. Therefore, the training and testing from the predicate devices still fits. Additional validation was performed on a test dataset independent from the original training/validation/test datasets. The evaluation on the test dataset confirmed significant improvements of Deep Resolve Boost in terms of the metrics peak signal-to-noise ratio (PSNR) and structural similarity index (SSIM) compared to conventional GRAPPA as the reference.
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 predicate devices submission (K252838). Additional tests have been performed to evaluate the applicability of the network to the TSE_DIXON, SE and SE_17RB130 pulse sequence types.
	Dataset split:

	Training: more than 23250 slices (93%) Validation: more than 1750 slices (7%) Additional test dataset for SE and TSE_DIXON: more than 1300 slices 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 of Deep Resolve Boost (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 the pulse sequence types SE, SE_17RB130 and TSE_DIXON were not part of the training/validation dataset and are therefore independent.

Deep Resolve Boost for TFL / MPRAGE imaging:

Test result summary	Compared to the predicate devices, there are no changes as the function has not been modified. Additional evaluation was performed on an independent test dataset using quantitative metrics such as structural similarity index (SSIM), peak signal-to-noise ratio (PSNR) and mean squared error (MSE) metrics compared to the conventional algorithm. 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 MRI scanners Protocols: representative protocols (T1, T2 and PD with and without fat saturation) which have been altered (e.g. to increase SNR, increase resolution or reduced acceleration) Body regions: broad range of different body regions Used coils: broad range of coils to cover the dedicated body regions
	Sample size: 27679 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.
	Gender distribution:

Patient characteristics	- 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 TFL / MPRAGE imaging:

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. 13,601 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.

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

10. Clinical Tests / Publications

No additional clinical tests were conducted to support substantial equivalence for the subject devices; however, as stated above, sample clinical images were provided. Clinical publications were referenced to provide information on the use of some of the features and functions.

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.

MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise and MAGNETOM Flow.Pure with software Syngo MR XB20A 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. Conclusion as to Substantial Equivalence

MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise and MAGNETOM Flow.Pure with software Syngo MR XB20A have similar intended use and same basic technological characteristics than the predicate device systems, MAGNETOM Flow.Elite, MAGNETOM Flow.Neo and MAGNETOM Flow.Rise with Syngo MR XB10A, with respect to the magnetic resonance features and functionalities. While there are some 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 devices and reference devices.

Siemens believes that MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise and MAGNETOM Flow.Pure with software Syngo MR XB20A are substantially equivalent to the currently marketed devices MAGNETOM Flow.Elite, MAGNETOM Flow.Neo and MAGNETOM Flow.Rise with software Syngo MR XB10A (K252838, cleared on December 19, 2025).