February 23, 2026

Siemens Shenzhen Magnetic Resonance , Ltd.
Martin Rajchel
Sr. Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
40 Liberty Blvd.
Malvern, Pennsylvania 19355

Re: K260265
Trade/Device Name: MAGNETOM Flow.Ace; MAGNETOM Flow.Plus
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: January 26, 2026
Received: January 28, 2026

Dear Martin Rajchel:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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.	K260265

Please provide the device trade name(s).

MAGNETOM Flow.Ace;
MAGNETOM Flow.Plus

Please provide your Indications for Use below.

The indications for use for the subject devices:

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.

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

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

510(k) Summary

K260265

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:

February, 16, 2026

Manufacturer:

Siemens Shenzhen Magnetic Resonance Ltd.
Siemens MRI Center, Gaoxin C. Ave., 2nd
Hi-Tech Industrial Park
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA
Registration Number: 3004754211

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

2. Contact Information

Martin Rajchel
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Siemens Medical Solutions USA, Inc.
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Malvern, PA 19355, USA
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E-mail: martin.rajchel@siemens-healthineers.com

3. Device Name and Classification

Device/ Trade name:	MAGNETOM Flow.Ace MAGNETOM Flow.Plus
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 Devices and Reference Device

4.1 Predicate Devices

Trade name:	MAGNETOM Flow.Ace MAGNETOM Flow.Plus
510(k) Number:	K250436
Clearance Date:	June 16, 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

4.2 Reference Devices

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

5. Indications for Use

The indications for use for the subject devices are the same as for the predicate devices:

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.Ace & MAGNETOM Flow.Plus with software Syngo MR XB10 include new and modified hardware and software compared to the predicate devices, MAGNETOM Flow.Ace & MAGNETOM Flow.Plus with software syngo MR XA70A. A high-level summary of the **new and modified hardware and software** is provided below:

Type	**Modification Type for subject devices**	**Feature**
Hardware	**New** compared to predicate	- Spine support respiratory (Cushion) as a part of BM Spine Coil Set 1.5T (including new surface material)
Software	**New** same as predicate, but with new Upgrade Option	- Gradient Configuration Upgrade
Other Modifications and / or Minor Changes	**Modified** same as predicate, but with new claim introduced	- PETRA (new claim for the existing sequence)

In addition, the following hardware and software are **transferred** from the reference device MAGNETOM Flow.Neo with software Syngo MR XB10 (K252838), to the subject devices **without any modifications**:

Type	**Modification Type for subject devices**	**Feature**
Hardware	**New** compared to predicate, same as reference (K252838) **(transferred without modifications)**	- BioMatrix Dockable Table with / without eDrive - Comfort Sound: Cushion
	Modified compared to predicate, same as reference (K252838) **(transferred without modifications)**	- Comfort Sound: BM Head/Neck Coil - Relocatable Option

Software	**New** compared to predicate, same as reference (K252838) **(transferred without modifications)**	- Open Workflow
	Modified compared to predicate, same as reference (K252838) **(transferred without modifications)**	- BioMatrix Motion Sensor (SAMER) - CS_VIBE - SPAIR FatSat Improvements: SPAIR “Abdomen & Pelvis” mode and SPAIR Breast mode - Deep Resolve Boost for FL3D_VIBE and SPACE - Deep Resolve Sharp for FL3D_VIBE and SPACE - Preview functionality for Deep Resolve Boost - myExam Implant Suite - GRE_PC - Open Recon 2.0 - Deep Resolve Boost for TSE - “MTC Mode” for SPACE
Other Modifications and / or Minor Changes	**New** compared to predicate, same as reference (K252838) **(transferred without modifications)**	- Eco Power Mode Pro
	Modified compared to predicate, same as reference (K252838) **(transferred without modifications)**	- Off-Center Planning Support - Flip Angle Optimization (Lock TR and FA) - ID Gain (re-naming) - Marketing bundle “myExam Companion”

7. Substantial Equivalence

MAGNETOM Flow.Ace & MAGNETOM Flow.Plus with software Syngo MR XB10 are substantially equivalent to the following **predicate devices**:

Predicate Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Flow.Ace with syngo MR XA70A	K250436, cleared on June 16, 2025	LNH LNI, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Flow.Plus with Syngo MR XA70A	K250436, cleared on June 16, 2025	LNH LNI, MOS	Siemens Shenzhen Magnetic Resonance Ltd.

MAGNETOM Flow.Ace & MAGNETOM Flow.Plus with software Syngo MR XB10 include hardware and software already cleared on the following **reference device**:

Reference Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Flow.Neo with Syngo MR XB10	K252838, cleared on December 19, 2025	LNH LNI, MOS	Siemens Healthineers AG

8. Comparison of technological Characteristics with the Predicate Devices

The subject devices, MAGNETOM Flow.Ace & MAGNETOM Flow.Plus with software Syngo MR XB10 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.

There are some differences in technological characteristics between the subject devices and predicate devices, including new and modified hardware and software features. These differences have been tested and the conclusion from the non-clinical and clinical data suggests that the features bear an equivalent safety and performance profile to that of the predicate devices. Please see below Table 1 and Table 2 for the comparison between subject devices and predicate/ reference devices.

Table 1: Hardware Comparison

Hardware	Subject Devices		Predicate Devices		Reference Device
	MAGNETOM Flow.Ace with Syngo MR XB10	MAGNETOM Flow.Plus with Syngo MR XB10	MAGNETOM Flow.Ace with syngo MR XA70A	MAGNETOM Flow.Plus with syngo MR XA70A	MAGNETOM Flow.Neo with Syngo MR XB10
Magnet System	Yes, same as predicate, but with relocatable option (same as reference)		Yes		Yes
RF System	Yes, same as predicate device		Yes		Yes
Transmission technique – RF Body Coil	Yes, same as predicate device		Yes		Yes
Gradient System	Yes, same as predicate device, but with a new Gradient Configuration Upgrade from B60 to G60		Yes		Yes
Patient Table	Yes, new compared to predicate, but same as reference: - BioMatrix Dockable Table with / without eDrive		Yes		Yes
Computer	Yes, same as predicate device		Yes		Yes
Coils	Yes, modified compared to predicate, but same as reference: - Comfort Sound for BM Head/Neck Coil		Yes		Yes

Other HW components	Yes, new compared to predicate: -Spine support respiratory (Cushion) as a part of BM Spine Coil Set 1.5T (including new surface material) Yes, new compared to predicate, but same as reference: - Comfort Sound Cushion	Yes	Yes

Table 2. Software Features Comparison

Hardware	Subject Devices		Predicate Devices		Reference Device
	MAGNETOM Flow.Ace with Syngo MR XB10	**MAGNETOM Flow.Plus with Syngo MR XB10**	**MAGNETOM Flow.Ace with syngo MR XA70A**	**MAGNETOM Flow.Plus with syngo MR XA70A**	**MAGNETOM Flow.Neo with Syngo MR XB10**
Sequences					
SE-based pulse sequence types	Yes, modified compared to predicate, but same as reference: SE: - with ID Gain TSE: - with Deep Resolve Boost improvement - with Preview functionality for Deep Resolve Boost - with SPAIR "Abdomen&Pelvis" mode and SPAIR Breast mode - with ID Gain TSE_DIXON: - with ID Gain HASTE: - with Deep Resolve Boost (e.g. preview functionality) - with SPAIR “Abdomen&Pelvis” mode and SPAIR Breast mode SPACE: - with "MTC Mode" improvement - with Deep Resolve Boost (e.g. preview functionality) - with Deep Resolve Sharp - with SPAIR “Abdomen&Pelvis” mode and SPAIR Breast mode BLADE: - with SPAIR “Abdomen&Pelvis” mode and SPAIR Breast mode		Yes		Yes

GRE-based/Steady-State Pulse Sequence Types	Yes, modified compared to predicate, but same as reference: FL3D_VIBE: - with Deep Resolve Boost (e.g. preview functionality) - with Deep Resolve Sharp - with Compressed Sensing (CS-Vibe) - with SPAIR “Abdomen&Pelvis” mode and SPAIR Breast mode TurboFLASH (TFL): - with BioMatrix Motion Sensor (SAMER) GRE_PC: - in-plane generalized auto calibrating parallel acquisition (GRAPPA)-based SMS formulation	Yes	Yes
EPI-based Pulse Sequence Types	Yes, modified compared to predicate, but same as reference: EP2D_DIFF: - with Deep Resolve Boost (e.g. preview functionality) - with SPAIR “Abdomen&Pelvis” mode and SPAIR Breast mode RESOLVE: - with SPAIR “Abdomen&Pelvis” mode and SPAIR Breast mode	Yes	Yes
Spectroscopy Pulse Sequence Types	Yes, same as predicate device	Yes	Yes
Feature and Applications			
Inline post-processing functions	Yes, modified compared to predicate, but same as reference: - with Flip Angle Optimization (Lock TR and FA)	Yes	Yes
Application Suites	Yes, same as predicate device	Yes	Yes
myExam	Yes, same as predicate device	Yes	Yes
Other Imaging Applications	Yes, modified compared to predicate, but same as reference: - myExam Implant Suite	Yes	Yes
Other Tim Suites	Yes, same as predicate device	Yes	Yes
Visualization	Yes, same as predicate device	Yes	Yes
Basic Post-Processing	Yes, same as predicate device	Yes	Yes
Communication	Yes, same as predicate device	Yes	Yes

Application and post-processing	Yes, new compared to predicate, but same as reference: - Open Workflow Framework Yes, modified compared to predicate, but same as reference: - Open Recon Framework	Yes	Yes
Other Software Feature / Application	Yes, same as predicate device	Yes	Yes
Software Platform and General Workflow	Yes, new compared to predicate, but same as reference: - Eco Power Mode Pro	Yes	Yes
Other Modifications / Minor Changes	Yes, same as predicate, but new claim introduced - PETRA Yes, modified compared to predicate, but same as reference: - Off-Center Planning Support - Marketing bundle “myExam Companion”	Yes	Yes

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	claim evidence	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
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 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.

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 as claim evidence only. Clinical publications were referenced to provide information on the use of the following features and functions.

Feature / Function	Clinical Publication
BioMatrix Motion Sensor (SAMER)	[1] Polak D, Splitthoff DN, Clifford B, Lo W-C, Huang SY, Conklin J, Wald LL, Setsompop K, Cauley S: Scout accelerated motion estimation and reduction (SAMER); Magn Reason Med 87:163-178 (2022). https://doi.org/10.1002/mrm.28971
	[2] Lang M, Tabari A, Polak D, Ford J, Clifford B, Lo W-C, Manzoor K, Splitthoff DN, Wald LL, Rapalino O, Schaefer P, Conklin P, Cauley S, Huang SY: Clinical Evaluation of Scout Accelerated Motion Estimation and Reduction Technique for 3D MR Imaging in the Inpatient and Emergency Department Settings; Am J Neuroradiol 44:125-133 (2023). https://doi.org/10.3174/ajnr.A7777
CS_VIBE	[3] Vreemann, S., Rodriguez-Ruiz, A., Nickel, D., Heacock, L., Appelman, L., van Zelst, J., Karssemeijer, N., Weiland, E., Maas, M., Moy, L., Kiefer, B., & Mann, R. M. (2017). Compressed Sensing for Breast MRI: Resolving the Trade-Off Between Spatial and Temporal Resolution. Investigative Radiology, 52(10), 574–582. https://doi.org/10.1097/rli.0000000000000384
PETRA	[4] Grodzki DM, Jakob PM, Heismann B. Ultrashort echo time imaging using pointwise encoding time reduction with radial acquisition (PETRA). Magn Reson Med. 2012 Feb;67(2):510-8. doi: 10.1002/mrm.23017. Epub 2011 Jun 30. PMID: 21721039.
	[5] Li C, Magland JF, Zhao X, Seifert AC, Wehrli FW. Selective in vivo bone imaging with long-T2 suppressed PETRA MRI. Magn Reson Med. 2017 Mar;77(3):989-997. doi: 10.1002/mrm.26178. Epub 2016 Feb 24. PMID: 26914767.

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 Shenzhen Magnetic Resonance Ltd. 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.Ace & MAGNETOM Flow.Plus with software 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	ANSI AAMI 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.Ace & MAGNETOM Flow.Plus with software Syngo MR XB10 have the same intended use and same basic technological characteristics as the respective predicate device systems, MAGNETOM Flow.Ace & MAGNETOM

Flow.Plus with software syngo MR XA70A, 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 device and reference devices.

Siemens believes that MAGNETOM Flow.Ace & MAGNETOM Flow.Plus with software Syngo MR XB10 are substantially equivalent to the currently marketed MAGNETOM Flow.Ace & MAGNETOM Flow.Plus with software syngo MR XA70A (K250436, cleared on June 16, 2025).