



June 16, 2025

Siemens Shenzhen Magnetic Resonance Ltd.
% Goodman Alina
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, Pennsylvania 19355

Re: K250436

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: May 20, 2025
Received: May 20, 2025

Dear Goodman Alina:

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,

Ningzhi Digitally
Li -S 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

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.

K250436

?

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

?

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
Mail Code 65-1A
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared: January 27th, 2025

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

Alina Goodman
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
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Malvern, PA 19355, USA
Phone: +1(224)526-1404
Fax: (610) 448-1787
E-mail: alina.goodman@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 and Reference Device

4.1. Predicate 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

4.2. Reference Device

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

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 Amira
510(k) Number: K223343
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
Classification Name: Picture Archiving and Communications System
Classification Panel: Radiology
CFR Code: 21 CFR §892.2050

Classification: Class II
Product Code: LLZ

5. Intended Use / Indications for Use

The indications for use for the subject devices are 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

With the subject software version, *syngo* MR XA70A, we are introducing the following new 1.5T devices, which are part of our MAGNETOM Flow. Platform:

- MAGNETOM Flow.Ace
- MAGNETOM Flow.Plus

MAGNETOM Flow.Ace and MAGNETOM Flow.Plus are 60cm-bore MRI systems, each featuring a quench pipe-free, sealed magnet that utilizes DryCool technology. The DryCool technology was initially introduced and cleared with the 0.55T reference device MAGNETOM Free.Max (K231617), now it is expanded across the portfolio from 0.55T to the new 1.5T subject devices.

Equipped with BioMatrix technology that adapts to patient's physiology, the subject devices also come with Siemens latest software platform *syngo* MR XA70A. With this software platform, the latest improvements enable the streamlining of operational efficiency with an improved patient-side workflow in the scanner room with patient registration, positioning and starting of the scan.

The Eco Power Mode technology is included for the subject devices and works by periodically switching off the cold head compressor during system standby or power off. This, in combination with the DryCool technology, reduces both energy and helium consumption of the subject devices.

MAGNETOM Flow.Ace and MAGNETOM Flow.Plus have different gradient configurations which are suited for examinations for all body regions. With the stronger gradient configuration, additional applications, including advanced cardiac imaging, can be supported.

The subject devices MAGNETOM Flow.Ace and MAGNETOM Flow.Plus with software version *syngo* MR XA70A, consists of new and modified hardware and software comparing to the predicate device MAGNETOM Sola with software *syngo* MR XA61A (K232535):

<u>Hardware</u>	<u>New Hardware</u>	- New Magnet - New Gradient Coil - New RF System - New Local Coils - New Patient Tables - New Computer Systems
<u>Software</u>	<u>New Features and Applications</u>	- AutoMate Cardiac - Quick Protocols - BLADE with SMS acceleration for non-diffusion imaging - Deep Resolve Swift Brain - Fast GRE Reference Scan - Ghost reduction - Fleet Reference Scan - SMS Averaging - Select&GO extension - myExam Spine Autopilot - New Startup-Timer
	<u>Modified Features and Applications</u>	- Improvements for Pulse Sequence Type SPACE - Improved Gradient ECO Mode Settings - Inline Image Filter switchable for users

7. Substantial Equivalence

MAGNETOM Flow.Ace and MAGNETOM Flow.Plus with software *syngo* MR XA70A are substantially equivalent to the predicate device and includes migrated features from the following reference devices:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Sola with <i>syngo</i> MR XA61A	K232535, cleared on December 22, 2023	LNH, LNI, MOS	Siemens Healthcare GmbH
Reference Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Cima.X with <i>syngo</i> MR XA61A	K231587, cleared on December 18, 2023	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Free.Max with <i>syngo</i> MR XA60A	K231617, cleared on November 09, 2023	LNH, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Amira with <i>syngo</i> MR XA50M	K223343, cleared on March 28, 2023	LNH, LNI, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
<i>syngo</i> .via VB40A	K191040, cleared on May 16, 2019	LLZ	Siemens Healthcare GmbH

8. Technological Characteristics

The subject devices, MAGNETOM Flow.Ace and MAGNETOM Flow.Plus with software *syngo* MR XA70A, are 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.

There are some differences in technological characteristics between the subject devices and predicate device, including 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 device.

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 software features, pulse sequence types	Guidance for Submission of Premarket Notifications for

Image quality assessment by sample clinical images	- new / modified pulse sequence types. - comparison images between the new / modified features and the predicate device features	Magnetic Resonance Diagnostic Devices
Performance bench test	- SNR and image uniformity measurements for coils - Heating measurements for coils	
Software verification and validation	mainly new and modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

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

AI Features/Applications training and validation:

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

	Deep Resolve Boost:	Deep Resolve Sharp:	Deep Resolve Swift Brain:
Training and Validation data	- TSE: more than 25,000 slices - HASTE: pre-trained on the TSE dataset and refined with more than 10,000 HASTE slices - EPI Diffusion: more than 1,000,000 slices The data covered a broad range of body parts, contrasts, fat suppression techniques, orientations, and field strength.	on more than 10,000 high resolution 2D images. The data covered a broad range of body parts, contrasts, fat suppression techniques, orientations, and field strength.	29,740 2D slices: - Training: 20,076 slices 1.5T Validation: 3,616 slices; 3T Validation: 6,048 slices
Test Statistics and Test Results Summary	The impact of the network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR) and structural similarity index (SSIM). Most	The impact of the network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR), structural similarity index (SSIM), and perceptual loss. In	The impact of the network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR), structural similarity index (SSIM) and normalized mean squared error (NMSE). Additionally, images were inspected visually

	importantly, the performance was evaluated by visual comparisons to evaluate e.g., aliasing artifacts, image sharpness and denoising levels.	addition, the feature has been verified and validated by inhouse tests. These tests include visual rating and an evaluation of image sharpness by intensity profile comparisons of reconstructions with and without Deep Resolve Sharp.	to ensure that potential artefacts are detected that are not well captured by the metrics listed above. After successful passing of the quality metrics tests, work-in-progress packages of the network were delivered and evaluated in clinical settings with collaboration partners.
Equipment	1.5T and 3T MRI systems		
Clinical Subgroups	No clinical subgroups have been defined for the collected dataset.		
Demographic Distribution	Due to reasons of data privacy, we did not record gender, age and ethnicity during data collection.		
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 under-sampling of the data by discarding k-space lines, lowering of the SNR level by addition of noise and mirroring of k-space data.	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.	The acquired datasets 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 under-sampling of the data by discarding k-space lines, lowering of the SNR level by addition of Gaussian noise to k-space data and uniformly-random cropping of the training data along the readout direction.

10. Clinical Tests / Publications

In order to practically learn Peripheral Nerve Stimulation (PNS) effects of the subject system, a clinical study of 12 individuals were conducted (see Results of stimulation study in Attachment 12.2).

No clinical tests were conducted to support substantial equivalence for the subject devices; however, as stated above, sample clinical images were provided.

Furthermore, additional clinical publications were referenced to provide information on the use of the following features and functions:

Feature	Publications
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Deep Resolve Swift Brain	[1] Pruessmann KP, Weiger M, Scheidegger MB, Boesiger P. SENSE: Sensitivity encoding for fast MRI. <i>Magn Reson Med</i>. 1999;42:952-962. [2] Demir et al., Optimization of Magnetization Transfer Contrast for EPI FLAIR Brain Imaging, <i>Magn Reson Med</i>. 2022;87:2380-2387. DOI: 10.1002/mrm.29141 [3] Yu S, Park B, Jeong J. Deep iterative down-up CNN for image denoising. In: <i>Proc. IEEE Conf. Comput. Vis. Pattern Recognit.</i>; 2019:9. [4] Hammernik K, Schlemper J, Qin C, Duan J, Summers RM, Rueckert D. Σ-net: Systematic evaluation of iterative deep neural networks for fast parallel MR image reconstruction. <i>ArXiv191209278</i> Cs Eess. December 2019. http://arxiv.org/abs/1912.09278. Accessed January 9, 2020. [5] Hammernik K, Schlemper J, Qin C, Duan J, Summers RM, Rueckert D. Systematic evaluation of iterative deep neural networks for fast parallel MRI reconstruction with sensitivity-weighted coil combination. <i>Magn. Reson. Med</i>. 2021;86(4):1859-1872. doi:10.1002/mrm.28827 [6] Wang Z, Bovik AC, Sheikh HR, Simoncelli EP. Image quality assessment: From error visibility to structural similarity. <i>IEEE Trans Image Process</i>. 2004;13(4):600-612. doi:10.1109/TIP.2003.819861 [7] Clifford et al., An artificial intelligence-accelerated 2-minute multi-shot echo planar imaging protocol for comprehensive high-quality clinical brain imaging, <i>Magn Reson Med</i>. 2022;87:2453–2463, DOI: 10.1002/mrm.29117 [8] Zbontar J, Knoll F, Sriram A, et al. fastMRI: An open dataset and benchmarks for accelerated MRI. <i>arXiv:181108839</i> [physics, stat]. December 2019. http://arxiv.org/abs/1811.08839. Accessed March 5, 2020. [9] Altmann et al., Ultrafast Brain MRI Protocol at 1.5 T Using Deep Learning and Multi-shot EPI, <i>Acad Radiol</i>, Volume 30, Issue 12, P2988-2998, December 2023, DOI: https://doi.org/10.1016/j.acra.2023.04.019 [10] Altmann et al., Ultrafast Brain MRI with Deep Learning Reconstruction for Suspected Acute Ischemic Stroke, <i>Radiology</i> 2024; 310(2):e231938, https://doi.org/10.1148/radiol.231938
	[11] Xie Y, Yang Q, Xie G, Pang J, Fan Z, Li D: Improved black-blood imaging using DANTE-SPACE for simultaneous carotid and intracranial vessel wall evaluation, <i>Magn Reson Med</i>, 2016 Jun, 75(6):2286-94. doi: 10.1002/mrm.25785. Epub 2015 Jul 8. PMID: 26152900; PMCID: PMC4706507 [12] Li L, Miller KL, Jezzard P: DANTE-prepared pulse trains: a novel approach to motion-sensitized and motion-suppressed quantitative magnetic resonance imaging, <i>Magn Reson Med</i>, 2012 Nov, 68(5):1423-38. doi: 10.1002/mrm.24142. Epub 2012 Jan 13. PMID: 22246917 [13] Tagawa H, Fushimi Y, Funaki T, Nakajima S, Sakata A, Okuchi S, Hinoda T, Grinstead J, Ahn S, Hidaka Y, Yoshida K, Miyamoto S, Nakamoto Y: Vessel wall MRI in moyamoya disease: arterial wall enhancement varies depending on age, arteries, and disease progression, <i>Eur Radiol</i>, 2023 Oct 5, doi: 10.1007/s00330-023-10251-9. Epub ahead of print. PMID: 37798407
SPACE Improvement	[14] Wang X, Greer JS, Dimitrov IE, Pezeshk P, Chhabra A, Madhuranthakam AJ: Frequency Offset Corrected Inversion Pulse for B0 and B1 Insensitive Fat Suppression at 3T: Application to MR Neurography of Brachial Plexus, <i>J Magn Reson Imaging</i>, 2018 Oct 48(4):1104-1111. doi: 10.1002/jmri.26021. Epub 2018 Sep 15. PMID: 30218576 [15] Mugler JP 3rd: Optimized three-dimensional fast-spin-echo MRI, <i>J Magn Reson Imaging</i>, 2014 Apr 39(4):745-67. doi: 10.1002/jmri.24542. Epub 2014 Jan 8. PMID: 24399498.

AutoMate Cardiac	[16] J. a. Y. S. S. a. S. M. Wetzl, "AI-based Single-Click Cardiac MRI Exam: Initial Clinical Experience and Evaluation in 44 Patients," in ISMRM & ISMRT Annual Meeting & Exhibition, 2023. [17] S. S. a. P. E. a. S. M. a. F. C. a. C. T. a. S. P. a. F. J. L. a. T. C. a. W. J. a. M. A. Yoon, "Automated Cardiac Resting Phase Detection Targeted on the Right Coronary Artery," Machine Learning for Biomedical Imaging, vol. 2, pp. 1-26, 2023. [18] S. S. a. S. M. a. R. M. a. C. T. a. S. P. a. E. T. a. T. C. a. W. R. Yoon, "Validation of a deep learning based automated myocardial inversion time selection for late gadolinium enhancement imaging in a prospective study," in ISMRM & ISMRT Annual Meeting & Exhibition, 2021. [19] R. a. K. T. a. S. Y. a. Y. a. S. Y. S. a. W. J. a. S. M. a. K. T. Ogawa, "Neural network-based fully automated cardiac resting phase detection algorithm compared with manual detection in patients," Acta Radiologica Open, vol. 11, no. 10, p. 20584601221137772, 2022. [20] S. a. W. J. a. S. M. a. B. M. a. Y. S. S. a. G. C. a. B. R. McDermott, "Albased Cardiac Scan Automation: A Prospective Comparison of Highly Automated Scan Workflows in 32 Patients," in Society for Cardiovascular Magnetic Resonance, 2024. [21] S. a. A. M. a. J. A. a. S. R. B. a. Z. T. a. K. M. a. S. J. a. T. E. a. C. E. a. S. C. Bohnen, "Cardiovascular magnetic resonance imaging in the prospective, population-based, Hamburg City Health cohort study: objectives and design," Journal of Cardiovascular Magnetic Resonance, vol. 20, pp. 1-11, 2018. [22] T. a. G. P. a. H. T. a. U. T. a. C. S. a. K. M. a. T. S. a. L. Y. a. M. M. C. a. S. F. Pezel, "Vasodilatation stress cardiovascular magnetic resonance imaging: Feasibility, workflow and safety in a large prospective registry of more than 35,000 patients," Archives of Cardiovascular Diseases, vol. 114, pp. 490-503, 2021. [23] G. a. P. A. U. a. K. K. P. a. N. R. a. H. R. a. W. J. a. Y. S. S. a. S. M. a. N. B. L. a. P. C. a. o. Wood, "Automated detection of cardiac rest period for trigger delay calculation for image-based navigator coronary magnetic resonance angiography," Journal of Cardiovascular
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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 adheres to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards. Furthermore, the devices are intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

MAGNETOM Flow.Ace and MAGNETOM Flow.Plus with software *syngo* MR XA70A 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	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
12-295	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 Ed. 3.2 b:2015	IEC
5-125	General	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	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	IEC
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic	MS 4-2010	NEMA

		Resonance Imaging Devices		
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) Set	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 Fifth edition 2018-08	ISO

12. Conclusion as to Substantial Equivalence

MAGNETOM Flow.Ace and MAGNETOM Flow.Plus with software *syngo* MR XA70A have the same intended use and same basic technological characteristics as the predicate device system, MAGNETOM Sola (with XJ gradient system) with *syngo* MR XA61A (K232535, cleared on December 22, 2023), with respect to the magnetic resonance features and functionalities. While there are some differences in technical features compared to the predicate device, 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 and MAGNETOM Flow.Plus with software *syngo* MR XA70A are substantially equivalent to the currently marketed device MAGNETOM Sola (with XJ gradient system) with *syngo* MR XA61A.