Siemens Medical Solutions USA, Inc.
℅ Karthik Pillai, Ph.D.
Senior Regulatory Affairs Professional
40 Liberty Boulevard
Mail Code 65-1A
MALVERN PA 19355

February 25, 2022

Re: K213693
Trade/Device Name: MAGNETOM Vida with syngo MR XA50A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI and MOS
Dated: February 1, 2022
Received: February 2, 2022

Dear Karthik Pillai:

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 (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 located 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.

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 803) for

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

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

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K213693

Device Name

MAGNETOM Vida with syngo MR XA50A

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 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.

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K213693

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: November 22, 2021

Manufacturer:
Siemens Healthcare GmbH
Henkestr. 127
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

Karthik Pillai, PhD
Senior Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355, USA
Phone: +1(317)371-8593
Fax: (610) 448-1787
E-mail: karthik.pillai@siemens-healthineers.com

3. Device Name and Classification

Device/ Trade name: MAGNETOM Vida with *syngo* MR XA50A
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 Vida
510(k) Number:	K203443
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. Intended 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 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 Vida with software *syngo* MR XA50A includes new and modified software compared to the predicate device, MAGNETOM Vida with software *syngo* MR XA31A. A high-level summary of the new and modified hardware and software is provided below:

Software

New Features and Applications

- **Deep Resolve Swift Brain** is a protocol for fast routine brain imaging primarily based on echo planar imaging (EPI) pulse sequences. Its main enablers are multi-shot (ms) EPI pulse sequence types and a deep learning-based image reconstruction.
- **Deep Resolve Boost** is a novel deep learning-based image reconstruction algorithm for 2D TSE data, which reconstructs images from k-space raw-data.
- **BLADE diffusion** is a multi-shot imaging method based on TSE or TGSE (when EPI factor > 1) readout and a BLADE trajectory with diffusion preparation to enable diffusion weighted imaging with reduced sensitivity to B0 inhomogeneity and reduced T2 decay caused image blurring.

- **HASTE diffusion** (HASTE_DIFF) is a single-shot imaging method based on TSE readout with diffusion preparation to enable diffusion weighted imaging with reduced sensitivity to B0 inhomogeneity.

Modified Features and Applications

- **Fast GRE RefScan**: A speed-optimized reference scan for GRAPPA and SMS kernel calibration for echo planar imaging pulse sequence types.
- **Static Field Correction** is a reconstruction option reducing susceptibility-induced distortions and intensity variations.
- **Deep Resolve Gain** is a reconstruction option which improves the SNR of the scanned images. The functionality has been extended to pulse sequence types SE and TSE_DIXON.
- **Deep Resolve Sharp** is an interpolation algorithm which increases the perceived sharpness of the interpolated images. The functionality has been extended to pulse sequence types SE and TSE_DIXON.
- The **myExam Angio Advanced Assist** provides an assisted and guided workflow for peripheral angiography examination using care bolus. The main advantage of this new workflow is a simplified and improved planning procedure of multi-station peripherical angiography measurements.

Other Modifications and / or Minor Changes

- **TSE MoCo** is an image-based motion correction in the average-dimension for the TSE pulse sequence type.
- MR Breast Biopsy is improved with an **automatic fiducial detection**.

7. Substantial Equivalence

MAGNETOM Vida with software *syngo* MR XA50A is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with *syngo* MR XA31A	K203443, cleared March 31, 2021	LNH LNI, MOS	Siemens Healthcare GmbH

8. Comparison of technological characteristics with the predicate device

The subject device, MAGNETOM Vida with software *syngo* MR XA50A, 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.

There are some differences in technological characteristics between the subject device and predicate device, including modified 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	new and modified software features	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Image quality assessments by sample clinical images. In some cases a comparison of the image quality / quantitative data was made.	- new / modified pulse sequence types and algorithms. - comparison images between the new / modified features and the predicate device features	
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.

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 the following features and functions.

Feature / Function	Clinical Publication
Deep Resolve Swift Brain	[1] Pruessmann KP, Weiger M, Scheidegger MB, Boesiger P. SENSE: Sensitivity encoding for fast MRI. Magn Reson Med. 1999;42:952-962.
	[2] Hyun CM, Kim HP, Lee SM, Lee S, Seo JK. Deep learning for undersampled MRI reconstruction. Phys Med Biol. 2018;63(13):135007. doi:10.1088/1361-6560/aac71a
	[3] Wang S, Su Z, Ying L, et al. Accelerating magnetic resonance imaging via deep learning. In: *2016 IEEE 13th International Symposium on Biomedical Imaging (ISBI)*. Prague, Czech Republic: IEEE; 2016:514-517. doi:10.1109/ISBI.2016.7493320
	[4] Yu S, Park B, Jeong J. Deep iterative down-up CNN for image denoising. In: Proc. IEEE Conf. Comput. Vis. Pattern Recognit.; 2019:9.
	[5] 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. ArXiv191209278 Cs Eess. December 2019. http://arxiv.org/abs/1912.09278. Accessed January 9, 2020.
	[6] 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. Magn. Reson. Med. 2021;86(4):1859-1872. doi:10.1002/mrm.28827

	[7] Wang Z, Bovik AC, Sheikh HR, Simoncelli EP. Image quality assessment: From error visibility to structural similarity. IEEE Trans Image Process. 2004;13(4):600-612. doi:10.1109/TIP.2003.819861
	[8] Schlemper J, Caballero J, Hajnal JV, Price AN, Rueckert D. A deep cascade of convolutional neural networks for dynamic MR image reconstruction," IEEE Trans. Med. Imag. 2018;37:491-503
	[9] Zbontar J, Knoll F, Sriram A, et al. fastMRI: An open dataset and benchmarks for accelerated MRI. arXiv:181108839 [physics, stat]. December 2019. http://arxiv.org/abs/1811.08839. Accessed March 5, 2020.
	[10] Demir et al., Optimization of Magnetization Transfer Contrast for EPI FLAIR Brain Imaging, Proceedings of the ISMRM 2021, abstract 4179
	[11] Clifford et al., Clinical evaluation of an AI-accelerated two-minute multi-shot EPI protocol for comprehensive high-quality brain imaging, Proceedings of the ISMRM 2021, abstract 300
	[12] Filho et al., Clinical Evaluation of An AI-Accelerated Two-Minute Multi-Shot EPI Protocol For Comprehensive High-Quality Brain MRI In An Emergency And Inpatient Setting, Proceedings of the RSNA 2021, accepted, abstract 16890
	[13] Pistocchi et al., AI-enhanced multi-shot multi-contrast EPI protocol: Preliminary clinical experience, Proceedings of the ECR 2022, submitted
Deep Resolve Boost	[14] Gassenmaier S et al., Deep learning–accelerated T2-weighted imaging of the prostate: Reduction of acquisition time and improvement of image quality, European Journal of Radiology, 137 (2021)
	[15] Herrmann J et al., Diagnostic Confidence and Feasibility of a Deep Learning Accelerated HASTE Sequence of the Abdomen in a Single Breath-Hold, Investigative Radiology, Volume 56, Number 5, May 2021
	[16] Shanbhogue K et al. Accelerated single-shot T2-weighted fat-suppressed (FS) MRI of the liver with deep learning-based image reconstruction: qualitative and quantitative comparison of image quality with conventional T2-weighted FS sequence. Eur Radiol. 2021 May 7.
	[17] Herrmann J et al., Development and Evaluation of Deep Learning-Accelerated Single-Breath-Hold Abdominal HASTE at 3 T Using Variable Refocusing Flip Angles. Invest Radiol. 2021 Apr 22.
	[18] Gassenmaier S et al., Accelerated T2-Weighted TSE Imaging of the Prostate Using Deep Learning Image Reconstruction: A Prospective Comparison with Standard T2-Weighted TSE Imaging, Cancers, 13, 3593 (2021)

	[19] Herrmann J et al., Feasibility and implementation of a Deep Learning MR reconstruction for TSE sequences in musculoskeletal imaging, Diagnostics, 11, 1484 (2021)
	Publications under review: [20] Judith Herrmann et al., Feasibility and diagnostic confidence of deep learning reconstructed TSE imaging of the knee at 1.5 and 3 T. A prospective study.
BLADE_Diffusion	[21] Alsop, D. C. (1997). Phase insensitive preparation of single shot RARE: application to diffusion imaging in humans. *Magnetic resonance in medicine*, 527-533.
	[22] Fu, Q., Kong, X.-c., Liu, D.-x., Guo, Y.-h., Zhou, K., Lei, Z.-q., & Zheng, C.-s. (2021). Clinical utility of turbo gradient and spin echo BLADE-DWI (TGSE-BLADE-DWI) for orbital tumors compared with readout-segmented echo-planar DWI. Proc. Intl. Soc. Mag. Reson. Med., (p. 3933).
	[23] Fu, Q., Kong, X.-c., Liu, D.-x., Guo, Y.-h., Zhou, K., Lei, Z.-q., & Zheng, C.-s. (2021). The efficacy 2D turbo gradient- and spin-echo diffusion-weighted imaging for cerebellopontine angle tumors. *Proc. Intl. Soc. Mag. Reson. Med.*, (p. 3934).
	[24] Hu, H. H., McAllister, A. S., Jin, N., Lubeley, L. J., Selvaraj, B.,Smith, M., . . . Zhou, K. (2019). Comparison of 2D BLADE turbo gradient-and spin-Echo and 2D spin-Echo Echo-planar diffusion-weighted brain MRI at 3 T: preliminary experience in children. *Academic radiology*, 1597-1604.
	[25] Pipe, J. G., Farthing, V. G., & Forbes, K. P. (2002). Multishot Diffusion-Weighted FSE UsingPROPELLER MRI. *Magnetic Resonance in Medicine* , 42-52.
	[26] Sheng, Y., Hong, R., Sha, Y., Zhang, Z., Zhou, K., & Fu, C. (2020). Performance of TGSE BLADE DWI compared with RESOLVE DWI in the diagnosis of cholesteatoma. *BMC medical imaging*, 1-9.
	[27] Srinivasan, G., Rangwala, N., & Zhou, X. J. (2018). Steer-PROP: a GRASE-PROPELLER sequence with interecho steering gradient pulses. *Magnetic resonance in medicine*, 2533-2541.
	[28] Yuan, T., Sha, Y., Zhang, Z., Liu, X., Ye, X., Sheng, Y., . . . Fu, C. (2020). TGSE diffusion-weighted pulse sequence in the evaluation of optic neuritis: Acomprehensive comparison of image quality with RESOLVE DWI. *Proc. Intl. Soc. Mag. Reson. Med.*, (p. 4137).
	[29] Zhou, K., Liu, W., & Cheng, S. (2018). Non-CPMG PROPELLER diffusion imaging: comparison of phase insensitive preparation with split acquisition. *Proc. Intl. Soc. Mag. Reson. Med.*, (p. 5320).

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 Vida with software *syngo* MR XA50A conforms 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
19-4	General II (ES/ EMC)	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	ES60601-1:2005/(R)2012 and A1:2012	ANSI AAMI
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
5-40	General I (QS/ RM)	Medical devices - Application of risk management to medical devices	14971 Second edition 2007-03-01	ISO
5-114	General I (QS/ RM)	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1:2015	ANSI AAMI IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	62304:2006/A1:2016	ANSI AAMI 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 (R2014)	NEMA
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 - 3.20 (2016)	NEMA
12-331	Radiology	Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems	Standards Publication MS 14-2019	NEMA

12. Conclusion as to Substantial Equivalence

MAGNETOM Vida with software *syngo* MR XA50A has the same intended use and same basic technological characteristics than the predicate device system,

MAGNETOM Vida with *syngo* MR XA31A, 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.

Siemens believes that MAGNETOM Vida with software *syngo* MR XA50A is substantially equivalent to the currently marketed device MAGNETOM Vida with software *syngo* MR XA31A (K203443, cleared on March 31, 2021).