Siemens Medical Solutions USA, Inc.
℅ Alina Goodman
Regulatory Affairs Professional
40 Liberty Blvd.
MALVERN PA 19355

April 29, 2022

Re: K220939
Trade/Device Name: MAGNETOM Lumina and MAGNETOM Vida Fit with *syngo* MR XA50A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: March 30, 2022
Received: March 31, 2022

Dear Alina Goodman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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
CAPT Patrick Hintz, MSIH, CIH, USPHS
Assistant Director
Eletronic Products Team
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.

510(k) Number *(if known)*
K220939

Device Name
MAGNETOM Lumina and MAGNETOM Vida Fit 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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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:

March 30, 2022

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

Alina Goodman
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Malvern, PA 19355, USA
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E-mail: alina.goodman@siemens-healthineers.com

3. Device Name and Classification

Device/ Trade name:	MAGNETOM Lumina and MAGNETOM Vida Fit 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 Devices

Trade name:	MAGNETOM Lumina with *syngo* MR XA31A
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

Trade name:	MAGNETOM Vida Fit with *syngo* MR XA20A
510(k) Number:	K192924
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 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 Lumina and MAGNETOM Vida Fit with software *syngo* MR XA50A include new software compared to the predicate devices, MAGNETOM Vida Fit with software *syngo* MR XA20A (K192924) and MAGNETOM Lumina with *syngo* MR XA31A (K203443). This software and some hardware components are transferred from the reference device MAGNETOM Vida with software *syngo* MR XA50A (K213693) as well as an imaging feature from MAGNETOM Vida with software *syngo* MR XA11A (K181433). A high-level summary of the transferred hardware and software is provided below:

Hardware (Vida Fit only)

Transferred Hardware:

- The **Nexaris Dockable Table** is a new variant of the MR patient table which is used for intraoperative or interventional imaging. It enables the patient transfer between OR tables and the MR system without repositioning on the MR patient table and vice versa during interventional procedures and surgeries. Additionally, it can be used for diagnostic imaging.
- The **Nexaris Head Frame** holds up to two Ultra Flex Large 18 coils. It can be used for head imaging in combination with the Nexaris Dockable Table when the patient is positioned on the transfer board but not pinned in a head clamp.
- Transferred MaRS **Computer**

Transferred Coil:

- The **Nexaris Spine 36** is used in combination with and without transfer board for body imaging on the Nexaris Dockable Table.

Transferred modifications for hardware:

- The **Beat Sensor** is a contact less method for generating **cardiac triggers** as an alternative to the already existing ECG or pulse triggers. It is based on a measurement of the modulation of a weak magnetic Pilot Tone, caused by conformation changes in conductive tissues.

Software

Transferred Features and Applications:

Vida Fit only:

- **SVS_EDIT** is a special variant of the SVS_SE pulse sequence type, which acquires two different spectra (one with editing pulses on resonance, one with editing pulses off resonance) within a single sequence.
- **BEAT_FQ_nav** allows the user to make use of navigator echo based respiratory gating for flow imaging to acquire 4D flow data. Both navigator echo based respiratory gating as well as flow imaging are part of the predicate device already. New is merely the combination of both.
- The **HASTE_interactive** pulse sequence type extends the existing HASTE pulse sequence type by offering the possibility to interactively change imaging parameters.
- **GRE_WAVE** is a special variant of the GRE pulse sequence type which allows larger acceleration factors, measuring one or two contrasts. GRE Wave results in higher signal-to-noise ratio for larger acceleration factors which can be leveraged to allow fast high-resolution 3D susceptibility-weighted imaging.
- The **myExam Prostate Assist** provides an assisted and guided workflow for prostate imaging. This automated workflow leads to higher reproducibility of slice angulation and coverage; this may support exams not having to be repeated.
- **Injector coupling** is a software application that allows the connection of certain contrast agent injectors to the MR system for simplified, synchronized contrast injection and examination start.

Lumina only:

- **Compressed Sensing GRASP-VIBE** is intended to be used in dynamic and/or non-contrast liver examinations to support patients who cannot reliably hold their breath for a conventional breath-hold measurement.

Lumina and Vida Fit:

- **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.

Transferred Modifications for Features and Applications:

Vida Fit only:

- The **AbsoluteShim** mode is a shimming procedure based on a 3-echo gradient echo protocol.
- The **3D ASL sequence (tgse_asl)** now provides relCBF maps, by implementing an additional M0 scan and performing the corresponding reconstruction method. It also provides BAT maps in multiple inversion time(multi-TI) imaging.

Lumina and Vida Fit:

- **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 Sharp** is an interpolation algorithm which increases the perceived sharpness of the interpolated images. Functionality is available for different pulse sequence types. (Newly transferred to Vida Fit)
- **Deep Resolve Gain** is a reconstruction option which improves the SNR of the scanned images. Functionality is available for different pulse sequence types. (Newly transferred to Vida Fit)
- 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 transferred Modifications and / or Minor Changes

Vida Fit only:

- **Elastography-AddIn** synchronizes settings between the Elastography sequence and the active driver.
- **HASTE MoCo** is an image-based motion correction in the average-dimension for the HASTE pulse sequence type.
- **Coil independent pulse sequences** remove the coil information from the pulse sequences and generate this information during run-time from automatic coil detection and localization.
- The **Needle Intervention AddIn** provides a user interface for workflow improvement of MR-guided needle interventions under real-time imaging conditions. It supports planning a needle trajectory, laser-based localization of the entry point as well as automatic slice positioning.
- The **PhaseRev Dot Addin/Component** supports the measurement workflow of the user by automatically flipping the direction of the phase encoding gradient.
- The adjustment mode **"offcenter"** triggers a transmitter adjustment method that is specialized for offcenter imaging. The transmitter adjustment determines the RF voltage that is required to excite a certain B1 field.

Lumina and Vida Fit:

- **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 Lumina and MAGNETOM Vida Fit with software *syngo* MR XA50A are substantially equivalent to the following predicate devices:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Lumina with *syngo* MR XA31A	K203443, cleared March 31, 2021	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Vida Fit with *syngo* MR XA20A	K192924, cleared on March 11, 2020	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA50A consist of hardware and software features previously cleared with the following reference device:

Reference Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with *syngo* MR XA50A	K213693, cleared February 25, 2022	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Vida with *syngo* MR XA11A	K181433, cleared October 19, 2018	LNH LNI, MOS	Siemens Healthcare GmbH

8. Comparison of technological characteristics with the predicate devices

The subject devices, MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA50A, 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 transferred hardware and software from the reference device. The transferred features and components have been tested and the conclusion 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
Verification and validation	Transferred hardware and software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices / 21 CFR §820.30

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

10. Clinical Tests

No additional clinical tests were conducted to support substantial equivalence for the subject devices.

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 Lumina and MAGNETOM Vida Fit with software *syngo* MR XA50A 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
19-4	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
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 - 3.20 (2016)	NEMA
19-8	General II (ES/ EMC)	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 4.0 2014-02	IEC
12-331	Radiology	Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems	Standards Publication MS 14-2019	NEMA
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. Conclusion as to Substantial Equivalence

MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA50A have the same intended use and same basic technological characteristics than the predicate device systems, MAGNETOM Lumina with *syngo* MR XA31A and MAGNETOM Vita Fit with *sygno* XA20A, with respect to the magnetic resonance features and functionalities. While there are some differences in technical features compared to the predicate device, the transfer of software features has been tested and the conclusion from all verification and validation data suggest

that the features bear an equivalent safety and performance profile to that of the predicate and reference devices.

Siemens believes that MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA50A are substantially equivalent to the currently marketed device MAGNETOM Lumina with syngo MR XA31A (K203443, cleared on March 31, 2021) and MAGNETOM Vida Fit with software *syngo* MR XA20A (K192924, cleared on March 11, 2020).