March 22, 2024

Siemens Medical Solutions USA, Inc.
Milind Dhamankar
Clinical Affairs and Regulatory Professional
40 Liberty Boulevard
Malvern, Pennsylvania 19355

Re: K232322
Trade/Device Name: MAGNETOM Terra; MAGNETOM Terra.X
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: March 1, 2024
Received: March 1, 2024

Dear Milind Dhamankar:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality 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.

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

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)*

K232322

Device Name

MAGNETOM Terra and MAGNETOM Terra.X

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, and that displays the internal structure and/or function of the head or extremities. Other physical parameters derived from the images may also be produced.
Additionally, the MAGNETOM system is intended to produce Sodium images for the head and Phosphorus spectroscopic images and/or spectra for whole body, excluding the head. 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.

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 1, 2024

Manufacturer:
Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen
Germany
Registration Number: 3002808157

2. Contact Information

Milind Dhamankar, M.D.
Clinical Affairs and Regulatory Professional
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3. Device Name and Classification

Device/ Trade name: MAGNETOM Terra
Classification Name: Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel: Radiology
CFR Code: 21 CFR § 892.1000
Classification: II
Product Code: Primary: LNH
Secondary: LNI, MOS

Device/ Trade name: MAGNETOM Terra.X
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 Terra
510(k) Number:	K183222
Clearance Date:	February 15, 2019
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 / Indications for Use

The indications for use for the subject devices is modified compared to the predicate device to accurately represent the weight limits in individual coils' intended population compared to the predicate device:

Indications for Use:

The MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, and that displays the internal structure and/or function of the head or extremities. Other physical parameters derived from the images may also be produced.

Additionally the MAGNETOM system is intended to produce Sodium images for the head and Phosphorus spectroscopic images and/or spectra for whole body, excluding the head. 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.

6. Device Description

MAGNETOM Terra and MAGNETOM Terra.X with software syngo MR XA60A include new and modified hardware and software compared to the predicate

device, MAGNETOM Terra with software syngo MR E12U. A high level summary of the new and modified hardware and software is provided below:

Hardware

New Hardware

- **Combiner (pTx to sTx)** (8Tx-1Tx Combiner Interface): Hardware component adaptor to connect single Tx local RF coils to the pTx system, combines the 8Tx channels to single channel mode.
- **MC-PALI**: New component for monitoring RF power on all transmit channels.
- **GSSU control unit**: The new GSSU including the new cardiac stimulation monitor board supports and enables the cardiac simulation monitoring separately and nearly independently from the OPS.

New Coil

- The **8Tx32Rx Head** coil is a 1H (proton) RF-coil with 8 transmit and 32 receive channels used for head applications usable in the 8ch pTx Mode. It features a 8TX transmit shell. There are enhancements to the software that controls SAR. By enabling B1 shimming or full 8ch pTx operation, the new 8TX array allows improved B1 transmit characteristics which increase both contrast and homogeneity in the brain.

Modified Hardware

- Main components such as:
  - Upgrade of **GPA** to increase the gradient performance which leads to an improvement of the imaging.
  - New **Host computer** hardware with increased performance and “dynamic research labeling” in the GUI
  - New **MaRS computer** hardware as successor of previous MaRS computer
  - Upgrade the **SEP** to the newest cooling cabinet series
  - The new **shim cabinet** ASC5 replaces two ACS4 shim cabinets.
- **Other components** such as:
  - **RFPA**: Modified to be used for 8ch pTx. Therefore, components for 1ch Tx are obsolete and were removed and control- and power modules are combined in one module instead.
  - Use of a common MR component which provides basic functionality that is required for all MAGNETOM system types. **RFCEL**_2G_light houses common MR components compatible with the MR environment but no specific 7T functionality is implemented and it is reduced in its functionality.
  - The multi-nuclear (**MNO**) option has been modified to be used in combination with the parallel transmit (pTx) technology. Therefore, components used for the SAR supervision are changed. Other components such as the coils are unchanged.
  - **OPS module**: The OPS implements the SAFE model using digital filters now. The parametrization of the filters and the processes are independent and separate for the peripheral and cardiac stimulation supervision.

- **Cover with UI update on PDD**: The cover has been modified to bring the system up to the Siemens Healthineers Design incl. the Numaris/X platform on the patent data display interface.

Software

New Features and Applications

- **Static B1 shimming:** B1 Shimming is available for nearby all the sequences and can be used offering an improved B1 homogeneity especially in the brain.
- **TrueForm (1ch compatibility mode):** Software function to run a multi-channel pTx coil in a virtual single channel mode.
- **Deep Resolve Boost** is a novel deep learning-based image reconstruction algorithm for 2D TSE data, which reconstructs images from k-space raw-data.
- **Deep Resolve Gain** is a reconstruction option which enables targeted denoising, resulting in improved SNR of the scanned images. The functionality is available for specific pulse sequence types now.
- **Deep Resolve Sharp** is a deep learning-based interpolation algorithm which increases the perceived sharpness of the interpolated images. The functionality has been ported from the reference device MAGNETOM Vida to the subject devices MAGNETOM Terra and MAGNETOM Terra.X.
- **Bias field correction** (marketing name: **Deep RxE**) is a deep learning image filter. The intention is to correct images by reducing residual B1 inhomogeneities (similar to a pre-scan normalize) to improve image quality for head and extremity imaging.
- The new **BEAT** pulse sequence type provides a combination of Time-Of-Flight (**TOF**) MR **angiography** and **Compressed Sensing (CS)** to reduce measurement time.
- **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.
- The **PETRA** pulse sequence type generates no additional perceivable noise above the general noise in the background.
- **TSE_DIXON** is a modified TSE (turbo spin echo) pulse sequence type for Dixon imaging.
- The **Compressed Sensing** (CS) functionality is now available for the **SPACE** pulse sequence type. Scan time can be reduced by the incoherent under-sampling of the k-space data. The usage of CS as well as the acceleration factor and other options can be freely selected by the user.
- The **Compressed Sensing** (CS) functionality is now available for the **TFL** pulse sequence type. Scan time can be reduced by the incoherent under-sampling of the k-space data. The usage of CS as well as the acceleration factor and other options can be freely selected by the user.

- **IDEA** which is a set of tools for developing sequences, image reconstruction programs, etc. is now available as well.
- The **Scientific Suite** supports scientific users by providing easy access to application-specific data for further processing and advanced image calculus.

Modified Features and Applications

- **EP2D_DIFF and TSE with SliceAdjust:** SliceAdjust is a framework which allows applying adjustment settings dynamically for individual slice measures during the acquisition.
- The Turbo Flash (**TFL**) is a GRE-based pulse sequence type which generates T1w, and FWS images. With **dynamic pTx** more coverage and a homogenous contrast is possible.

Modified Software / Platform

- **Stimulation monitoring**: Peripheral nerve stimulation and cardiac stimulation limits are supervised via the SAFE model, but with separate parameterizations now. Both SAFE models run independently.
- "**dynamic research labeling**": new Host computer hardware with increased performance and "dynamic research labeling" in the GUI

Other Modifications and / or Minor Changes

- **Intended use, SAR Calculation and Weight limit reduction for 31P/1H TxRx Flex Loop Coil:** Adaptation of the system intended use, by moving the weight limit from the system intended use to the RF coil intended use and adapting of SAR calculation. In addition, change of the intended population for the 31P/1H TxRx Flex Loop 7T coil.
- **X-upgrade for MAGNETOM Terra to MAGNETOM Terra.X (marked as new device):** The MAGNETOM Terra.X is a new 7T MRI System which is the result of an improvement of the MAGNETOM Terra - either ex-factory or by an upgrade on-site.
- Provide secure MR scanner setup for **DoD** (Department of Defense) Information Assurance compliance.

7. Substantial Equivalence

MAGNETOM Terra and MAGNETOM Terra.X with software syngo MR XA60A are substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Terra with syngo MR E12U	K183222, cleared February 15, 2019	LNH LNI, MOS	Siemens AG / Siemens Healthcare GmbH

MAGNETOM Terra and MAGNETOM Terra.X with software syngo MR XA60A include hardware and software already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with software syngo MR XA50A	K213693, cleared February 25, 2022	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Prisma with software syngo MR XA30A	K202014, cleared September 8, 2020	LNH LNI, MOS	Siemens Healthcare GmbH
syngo.via VB40A	K191040, cleared May 16, 2019	LLZ	Siemens Healthcare GmbH

8. Comparison of technological Characteristics with the Predicate Device

The subject devices, MAGNETOM Terra and MAGNETOM Terra.X with software syngo MR XA60A, 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.

While there are some differences in technological characteristics between the subject devices and predicate device, including new and modified hardware and software, these differences have been tested and the conclusions from the non-clinical data suggest 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	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 was made.	- new / modified pulse sequence types and algorithms. - comparison images between the new / modified features and the predicate device features	
Performance bench test	new and modified hardware	
Software verification and validation	new and modified hardware and software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Electrical, mechanical, structural, and related system safety test	complete system MAGNETOM Terra and MAGNETOM Terra.X	- AAMI / ANSI ES60601-1 - IEC 60601-2-33
Electrical safety and electromagnetic compatibility (EMC)	complete system MAGNETOM Terra.X	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.

Below table shows an executive summary of training and validation dataset of AI features (Deep Resolve Boost, Deep Resolve Sharp and Deep RxE) in the subject devices.

Training and validation dataset of AI features

	Deep Resolve Boost	**Deep Resolve Sharp**	**Deep RxE**
General / additional information	n.a.	The same function as on reference device MAGNETOM Vida which was ported to the subject devices MAGNETOM Terra and MAGNETOM Terra.X without significant modifications. The training and testing from the reference devices still fits.	A 4-step approach was performed: 1. During training the loss, as the difference to a ground truth, is monitored and the training step with the lowest test loss is taken as the final trained network. 2. Automated unit-tests are set-up to test the consistency of the generated output to a previously defined reference output 3. During verification, the performance of the network is tested on a phantom against the ground truth with a maximal allowed NRMSE of 11% (11% for the 2D network and 8.7% for the 3D network were achieved) 4. The trained final network was used in the clinical study.
Test setup	Equipment: 7T MRI scanners (from the predicate device) Protocols: Representative protocols (T1, T2 and PD	Equipment: 1.5T and 3T MRI scanners Protocols: Representative protocols (T1, T2 and PD with and	Equipment: 7T MRI MAGNETOM Terra and MAGNETOM Terra.X scanners

	with and without fat saturation), which have been altered (e.g., to increase SNR, increase resolution or reduced acceleration). Body regions: head and knee	without fat saturation) which have been altered (e.g. to increase SNR, increase resolution or reduced acceleration). Body regions: a broad range of different body regions	Protocols: Representative protocols (T1, T2 and PD with and without fat saturation) which have been altered (e.g., to increase SNR, increase resolution or using acceleration techniques or without acceleration). Body regions: head (44%) and knee (56%) Used coils: - 1Tx32Rx Head Coil 7T Clinic / per system - research 8Tx32Rx Head / per system - 1Tx28Rx Knee Coil 7T Clinic / per system - 23Na 1Tx32Rx Head 7T
	Sample size: 26,473 2D slices (6206 2D slices acquired at 7T)	Sample size: 13,977 2D slices	Sample size: 143,947/2410 (2D slices / 3D volumes)
	Dataset split: - Training: 24,599 slices - Validation: 1,874 slices	Dataset split: - Training: 11,920 slices - Validation: 2,057 slices	Dataset split: - Training: 119,955/2007 (2D/3D) - Validation and test: 23,992/404 (2D/3D)
	Note: Data split maintained similar data distribution (e.g., contrast, orientation, field strength, …) in both training and validation datasets.		All data from the two MR systems were separated into independent training, validation and test datasets
	Sample source: in-house measurements and collaboration partners	Sample source: in-house measurements	
Patient Characteristics	Clinical subgroups: No clinical subgroups have been defined for the datasets.		Gender distribution: - female: 56% - male: 41% - phantom: 3% Age: group ranges from 20 - 80 years. Clinical subgroups: No clinical subgroups

			have been defined for the datasets.
	Please note: due to reasons of data privacy, we did not record how many individuals the datasets belong to. Gender, age, and ethnicity distribution were also not recorded during data collection. Due to the network architecture, attributes like gender, age and ethnicity are not relevant to the training data.		Please note: Due to the network architecture, attributes like gender, age and ethnicity are not relevant to the training data.
Confounder	The input and output variables of the network have been derived from the same dataset so that no confounders exist for the training methodology.		
Reference standard	The acquired datasets represent the ground truth for the training and validation. Input data was retrospectively created from the ground truth by data manipulation 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.	Applying three different methods for bias field correction to the data, homodyne filtering, N4 and UNICORN.
Test statistics and test results	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). Additionally, images were inspected visually 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 cooperation partners. In a total of seven peer-reviewed publications 427 patients	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 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 reconstruction with and without Deep Resolve Sharp. Both tests show increased edge sharpness.	Two step test procedure. 1. During training, the test data set was used to validate how the network performed on unseen data. 2. During system tests, the standard deviation was determined, and the RMS error was calculated (against the ground truth). The tests show that Deep RxE increases image homogeneity in a reproduceable way on the receive profile. Images acquired with Deep RxE (DL bias

	were successfully scanned on 1.5T and 3T. The investigations covered following body regions: prostate, abdomen, liver, knee, hip, ankle, shoulder, hand, and lumbar spine. All publications have concluded that the work-in-progress package and the reconstruction algorithm can be beneficially used for clinical routine imaging. No cases have been reported where the network led to a misinterpretation of the images or where anatomical information has been altered, suppressed, or introduced. In most cases the new algorithm has been used to acquire images faster and significant time savings are reported.		field correction) are rated better for image quality than the ones acquired without it in the clinical study that was conducted.

10. Clinical Tests / Publications

On the predicate device MAGNETOM Terra, a clinical study of 35 individuals was conducted to determine the nerve stimulation thresholds used to limit the gradient system output. The observed parameters were used to set the PNS (Peripheral Nerve Stimulation) threshold level which is required in IEC 60601-2-33. This study is still valid for the subject devices MAGNETOM Terra and MAGNETOM Terra.X as the same gradient coil is used.

In addition to providing clinical sample images for some software modifications and the new 8Tx32Rx Head of the subject device, radiologist's evaluation reports from two U.S. board-certified radiologists have been provided. Where necessary the radiologists compared the subject and the predicate / reference device images. The radiologist's evaluation reports have comments on any observed artifacts and concerns those have been communicated with the user via labeling material.

A clinical investigation was conducted that covered parallel transmission technique, applications with faster image acquisition, Deep learning approaches and additional methods to enhance the clinical application range and a report summarizing the results was provided. The conclusion of the test was that the subject device can be used in the clinical routine with all applications and protocols examined in the clinical investigation according to the investigation plan.

Clinical publications are referenced to provide information on the use of the following features and functions.

Feature / Function	Clinical Publication
dynamic pTx for TFL (for MAGNETOM Terra.X only)	Cloos MA, Boulant N, Luong M, Ferrand G, Giacomini E, Le Bihan D, Amadon A. kT -points: short three-dimensional tailored RF pulses for flip-angle homogenization over an extended volume. Magn Reson Med. 2012 Jan;67(1):72-80. doi: 10.1002/mrm.22978. Epub 2011 May 16. PMID: 21590724.
	Majewski K. Simultaneous optimization of radio frequency and gradient waveforms with exact Hessians and slew rate constraints applied to kT-points excitation. Journal of Magnetic Resonance. 2021 May 1; 326:106941.
	Herrler, J, Liebig, P, Gumbrecht, R, et al. Fast online-customized (FOCUS) parallel transmission pulses: A combination of universal pulses and individual optimization. Magn Reson Med. 2021; 85: 3140-3153. https://doi.org/10.1002/mrm.28643
	Tanner, Mark, Giulio Gambarota, Tobias Kober, Gunnar Krueger, David Erritzoe, José P Marques, and Rexford Newbould. 2012. 'Fluid and White Matter Suppression with the MP2RAGE Sequence.' Journal of Magnetic Resonance Imaging: JMRI 35 (5): 1063-70. https://doi.org/10.1002/jmri.23532.
Weight limit reduction for 31P/1H TxRx Flex Loop Coil	Parasoglou, P, et al., 3D-Mapping of Phosphocreatine Concentration in the Human Calf Muscle at 7T: Comparison to 3T, Magn Reson Med. Author manuscript; available in PMC 2014 December 01, 2013 December, 70(6)
	Hooijmans M. T., et al., Spatially localized phosphorous metabolism of skeletal muscle in Duchenne muscular dystrophy patients: 24±month follow-up, https://doi.org/10.1371/journal.pone.0182086, August 1, 2017

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 Terra and MAGNETOM Terra.X with software syngo MR XA60A 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)	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, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	ANSI AAMI
19-8	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, Ed. 4.0:2014	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. 3.2:2015	IEC
5-125	General I (QS/ RM)	Medical devices - Application of risk management to medical devices	14971 Third edition 2019-12	ISO
5-114	General I (QS/ RM)	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	62366-1 Edition 1.0 2015-02	IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	IEC
2-258	Biocompatibility	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process	10993-1 Fifth edition 2018-08	ISO

12-342	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 - 3.20 2021e	NEMA
12-188	Radiology	Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images	MS 1:2008 (R2020)	NEMA
12-196	Radiology	Determination of Two-dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images	MS 2:2008 (R2020)	NEMA
12-187	Radiology	Determination of Image Uniformity in Diagnostic Magnetic Resonance Images	MS 3:2008 (R2020)	NEMA
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4:2010	NEMA
12-322	Radiology	Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging	MS 5:2018	NEMA
12-195	Radiology	Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI)	MS 6:2008 (R2014)	NEMA
12-315	Radiology	Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems	MS 8:2016	NEMA
12-288	Radiology	Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images	MS 9-2008 (R2020)	NEMA
12-298	Radiology	Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging Systems	MS 10 - 2010	NEMA
12-306	Radiology	Quantification and Mapping of Geometric Distortion for Special Applications	MS 12 - 2016	NEMA

12. Conclusion as to Substantial Equivalence

MAGNETOM Terra and MAGNETOM Terra.X with software syngo MR XA60A have the same intended use (although it is corrected) and same basic technological characteristics than the predicate device system, MAGNETOM Terra with syngo MR E12U, 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 Terra and MAGNETOM Terra.X with software syngo MR XA60A are substantially equivalent to the currently marketed device MAGNETOM Terra with software syngo MR E12U (K183222, cleared on February 15, 2019).