November 20, 2025

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

Re: K251822
Trade/Device Name: MAGNETOM Free.Max; MAGNETOM Free.Star
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH MOS

Dear Alina Goodman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on November 20, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter as an administrative correction to include the IFU for K251822, as it was inadvertently excluded from our SE letter dated November 20, 2025.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Daniel Krainak, OHT8: Office of Radiological Health, 301-796-0478, Daniel.Krainak@fda.hhs.gov.

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

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40 Liberty Boulevard
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Re: K251822
Trade/Device Name: MAGNETOM Free.Max;
MAGNETOM Free.Star
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: October 20, 2025
Received: October 20, 2025

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 (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,

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251822

Device Name
MAGNETOM Free.Max
MAGNETOM Free.Star

Indications for Use *(Describe)*

MAGNETOM Free.Max:

The MAGNETOM MR system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross-sectional images that display, 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 may also be produced. Depending on the region of interest, contrast agents may be used. These images and the physical parameters derived from the images when interpreted by a trained physician or dentist trained in MRI yield information that may assist in diagnosis.

The MAGNETOM MR system may also be used for imaging during interventional procedures when performed with MR-compatible devices such as MR Safe biopsy needles.

When operated by dentists and dental assistants trained in MRI, the MAGNETOM MR system must only be used for scanning the dentomaxillofacial region.

MAGNETOM Free.Star:

The MAGNETOM MR system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross-sectional images that display, 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 may also be produced. Depending on the region of interest, contrast agents may be used. These images and the physical parameters derived from the images 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.**

# 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:**

June 12, 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.
40 Liberty Boulevard
Malvern, PA 19355, USA
Phone: +1(224)526-1404
E-mail: alina.goodman@siemens-healthineers.com

## 3. Device Name and Classification

**Device/ Trade name:**

MAGNETOM Free.Max
MAGNETOM Free.Star

**Classification Name:**

Magnetic Resonance Diagnostic Device (MRDD)

**Classification Panel:**

Radiology

**CFR Code:**

21 CFR § 892.1000

| | |
|---|---|
| **Classification:** | II |
| **Product Code:** | Primary: LNH<br>Secondary: MOS |

## 4. Legally Marketed Predicate Device and Reference Device

### 4.1 Predicate Device

| | |
|---|---|
| **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<br>Secondary: MOS |

| | |
|---|---|
| **Trade name:** | MAGNETOM Free.Star |
| **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<br>Secondary: MOS |

### 4.2 Reference 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<br>Secondary: LNI, MOS |

| | |
|---|---|
| **Trade name:** | syngo.via VB40A[1] |
| **510(k) Number:** | K191040 |
| **Classification Name:** | Picture Archiving and Communications System |
| **Classification Panel:** | Radiology |
| **CFR Code:** | 21 CFR §892.2050 |
| **Classification:** | II |
| **Product Code:** | LLZ |

[1] The initial version VB40 was cleared on May 16, 2019 with K191040.
syngo.via VB80 is released via Non-Filing Justification.

## 5. Intended Use/ Indications for Use

**MAGNETOM Free.Max:**

The indications for use statement for the subject device MAGNETOM Free.Max with *syngo* MR XA80A has been updated compared to the predicate device MAGNETOM Free.Max with *syngo* MR XA60A, to include “dentist trained in MRI” as a new intended user group in the statement:

The MAGNETOM MR system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross-sectional images that display, 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 may also be produced. Depending on the region of interest, contrast agents may be used. These images and the physical parameters derived from the images when interpreted by a trained physician or dentist trained in MRI yield information that may assist in diagnosis.

The MAGNETOM MR system may also be used for imaging during interventional procedures when performed with MR-compatible devices such as MR Safe biopsy needles.

When operated by dentists and dental assistants trained in MRI, the MAGNETOM MR system must only be used for scanning the dentomaxillofacial region.

**MAGNETOM Free.Star:**

The indications for use for the subject device MAGNETOM Free.Star with *syngo* MR XA80A is the same as the predicate device MAGNETOM Free.Star with *syngo* MR XA60A:

The MAGNETOM MR system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross-sectional images that display, 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 may also be produced. Depending on the region of interest, contrast agents may be used. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist in diagnosis.

<u>Indications for use modification rationale for MAGNETOM Free.Max:</u>

The newly added intended user group in the subject device’s indications for use statement does not affect the functionality of the device to produce images that may assist in diagnosis as a magnetic resonance diagnostic device. The submitted nonclinical data and clinical data demonstrate that the subject device is as safe and effective as the predicate device. Therefore, the difference does not constitute a new intended use according to FDA Guidance “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”. The subject device has the same intended use as the predicate device.

## 6. Device Description

The subject devices MAGNETOM Free.Max and MAGNETOM Free.Star with software version *syngo* MR XA80A, consists of new and modified hardware and software features comparing to the predicate device MAGNETOM Free.Max and MAGNETOM Free.Star with software version *syngo* MR XA60A (K231617).

Below is a high-level summary of the new and modified hardware and software features compared to the predicate devices MAGNETOM Free.Max and MAGNETOM Free.Star with *syngo* MR XA60A:

**Hardware**

New hardware features:

- Dental coil (only for MAGNETOM Free.Max)
- High-end host
- *syngo* Workplace

Modified hardware features:

- MaRS
- Select&GO Display (TPAN_3G)

**Software**

New Pulse Sequences/ Software Features / Applications:

Only for MAGNETOM Free.Max:

- EP_SEG_FID_PHS
- EP2D_FID_PHS
- EP_SEG_PHS
- GRE_Proj
- GRE_PHS
- myExam Dental Assist
- Select&GO Dental
- Slice Overlapping

For both MAGNETOM Free.Max and MAGNETOM Free.Star:

- Eco Power Mode
- Extended Gradient Eco Mode
- System Startup Timer

Modified Features and Applications:

- myExam RT Assist (only for MAGNETOM Free.Max)
- Deep Resolve for HASTE

- Deep Resolve for EPI Diffusion
- Select&GO for dental (only for MAGNETOM Free.Max)
- Select&GO extension: Patient Registration and Start Scan
- SPACE improvement: MTC prep module

**Other Modifications and Minor Changes:**

- MAGNETOM Free.Max Dental Edition marketing bundle (only for MAGNETOM Free.Max)
- MAGNETOM Free.Max RT Pro Edition marketing bundle (only for MAGNETOM Free.Max)
- Off-Center Planning Support
- ID Gain

Below Table 1 shows an executive summary of training and validation dataset of AI feature Deep Resolve Boost in subject devices:

Table 1. Training and validation dataset of Deep Resolve Boost

| | **Deep Resolve Boost** |
|---|---|
| Training and Validation data | • TSE: more than 25,000 slices<br>• HASTE: pretrained on the TSE dataset and refined with more than 10,000 HASTE slices<br>• EPI Diffusion: more than 1,000,000 slices<br>The data covered a broad range of body parts, contrasts, fat suppression techniques, orientations, and field strength. |
| Sample source | In-house measurements and collaboration partners. |
| Equipment | 0.55T[1], 1.5T and 3T MRI scanners |
| Protocols | Representative protocols (T1, T2 and PD with and without fat saturation) which have been altered (e.g. to increase SNR, increase resolution or reduced acceleration). |
| Clinical subgroups | No clinical subgroups have been defined for the datasets. |
| Demongraphic distribution | Due to reasons of data privacy, we did not record gender, age and ethnicity during data collection. |
| Confounders | No confounders have been defined for the datasets. |
| 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 importantly, the performance was evaluated by visual comparisons to evaluate for example, aliasing artifacts, image sharpness and denoising levels.<br>The quality metrics evaluation was performed by conventional reconstruction of a set of test data (gold standard). This test data |

| | |
|---|---|
| | set was compared against a retrospectively undersampled copy of the test data, which was reconstructed with both conventional and Deep Resolve Boost reconstruction. The SSIM metric shows that the Deep Resolve reconstruction has significantly better structural similarity with the gold standard than the conventional reconstruction. Likewise, the PSNR metric shows that the Deep Resolve reconstruction has significantly better signal-to-noise ratio (SNR) than the conventional reconstruction.<br><br>Visual evaluation was performed by qualified readers. Pairs of images where the same dataset (or two consecutive scans) was reconstructed both with conventional and Deep Resolve Boost reconstruction were examined for image quality with a focus on aliasing artifacts, image sharpness and SNR. In conclusion, all images show that the Deep Resolve Boost reconstruction results in higher SNR, and superior sharpness. Deep Resolve reconstruction was not found to have caused artifacts. |
| 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. |
| Data independency | The dataset was randomly split into two independent training and validation datasets. Data split maintained similar data distribution in both training and validation datasets. |

[1] To confirm the applicability of the networks to 0.55T, additional validation of 0.55T datasets covering a broad range of body regions was performed both by calculating metrics and performing visual image comparisons.

## 7. Substantial Equivalence

MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA80A are substantially equivalent to the predicate devices and include migrated features from the following references devices (see Table 2):

Table 2. Predicate devices and reference devices

| **Predicate Device** | **FDA Clearance Number and Date** | **Product Code** | **Manufacturer** |
|---|---|---|---|
| MAGNETOM Free.Max with *syngo* MR XA60A | K231617, cleared on November 09, 2023 | LNH, MOS | Siemens Shenzhen Magnetic Resonance Ltd. |
| MAGNETOM Free.Star with *syngo* MR XA60A | K231617, cleared on November 09, 2023 | LNH, MOS | Siemens Shenzhen Magnetic Resonance Ltd. |
| **Reference Device** | **FDA Clearance Number and Date** | **Product Code** | **Manufacturer** |
| MAGNETOM Sola with *syngo* MR XA61A | K232535, cleared on December 22, 2023 | LNH, LNI, MOS | Siemens Healthcare GmbH |
| syngo.via VB40A[1] | K191040, cleared on May 16, 2019 | LLZ | Siemens Healthcare GmbH |

## 8. Technological Characteristics

The subject devices, MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA80A, are substantially equivalent to the predicate devices with regard to the operational environment, programming language, operating system and performance.

The subject devices conform to the standard for medical device software (IEC 62304) and other relevant IEC and NEMA standards.

There are some differences in technological characteristics between the subject devices and predicate devices, including new and modified hardware and software features. These differences have been tested and the conclusion from the non-clinical and clinical data suggests that the features bear an equivalent safety and performance profile to that of the predicate devices.
Please see below Table 3 and Table 4 for the comparison between subject devices and predicate/ reference devices.

Table 3. Hardware Comparison

<table>
<tr><th rowspan="2">Hardware</th><th colspan="2">Subject Devices</th><th colspan="2">Predicate Devices</th></tr>
<tr><th>MAGNETOM Free.Max with syngo MR XA80A</th><th>MAGNETOM Free.Star with syngo MR XA80A</th><th>MAGNETOM Free.Max with syngo MR XA60A (K231617)</th><th>MAGNETOM Free.Star with syngo MR XA60A (K231617)</th></tr>
<tr><td>Magnet System</td><td colspan="2">Yes, same as predicate device</td><td colspan="2">Yes</td></tr>
<tr><td>RF System</td><td colspan="2">Yes, same as predicate device</td><td colspan="2">Yes</td></tr>
<tr><td>Transmission technique – RF Body Coil</td><td colspan="2">Yes, same as predicate device</td><td colspan="2">Yes</td></tr>
<tr><td>Gradient System</td><td colspan="2">Yes, same as predicate device</td><td colspan="2">Yes</td></tr>
<tr><td>Patient Table</td><td colspan="2">Yes, same as predicate device</td><td colspan="2">Yes</td></tr>
<tr><td>Computer</td><td colspan="2">Yes, modified compared to predicate devices:<br>-new high-end host computer hardware<br>-new syngo Workplace<br>-modified MaRS hardware</td><td colspan="2">Yes</td></tr>
<tr><td>Coils</td><td>Yes, new coil compared to predicate device:<br>-Dental coil</td><td>Yes, same as predicate device</td><td colspan="2">Yes</td></tr>
<tr><td>Other HW components</td><td colspan="2">Yes, modified compared to predicate device:<br>-Select&GO display (TPAN 3G)</td><td colspan="2">Yes</td></tr>
</table>

Table 4. Software Features Comparison

| Software | Subject Devices | | Predicate Device | |
|---|---|---|---|---|
| | **MAGNETOM Free.Max with software *syngo* MR XA80A** | **MAGNETOM Free.Star with software *syngo* MR XA80A** | **MAGNETOM Free.Max with software *syngo* MR XA60A (K231617)** | **MAGNETOM Free.Star with software *syngo* MR XA60A (K231617)** |
| **Sequences** | | | | |
| **SE-based pulse sequence types** | Yes, with new and modified features compared to predicate devices:<br>-Slice Overlapping for TSE and TSE_DIXON<br>- Deep Resolve for HASTE<br>- SPACE improvement with MTC prep module | | Yes | |
| **GRE-based/Steady-State Pulse Sequence Types** | Yes, with new pulse sequences compared to predicate devices:<br>-GRE_PHS<br>-GRE_Proj | | Yes | |
| **EPI-based Pulse Sequence Types** | Yes, with new pulse sequences and modified features compared to predicate devices:<br>-Deep Resolve for EP2D_DIFF<br>-EP_SEG_PHS<br>-EP_SEG_FID_PHS<br>-EP2D_FID_PHS | | Yes | |
| **Feature and Applications** | | | | |
| **Application Suites** | Yes, with new feature: Dental Suite | Yes, same as predicate device | Yes | |
| **myExam AutoPilot** | Yes, same as predicate device | | Yes | |
| **myExam Assist** | Yes, with new and modified features:<br>-myExam Dental Assist<br>-myExam RT Assist | Yes, same as predicate device | Yes | |
| **Inline Postprocessing Functions** | Yes, same as predicate device | | Yes | |
| **Visualization** | Yes, same as predicate device | | Yes | |
| **Basic Post-Processing** | Yes, same as predicate device | | Yes | |
| **Communication** | Yes, same as predicate device | | Yes | |
| **Application and post-processing** | Yes, same as predicate device | | Yes | |
| **Other Software Feature / Application** | Yes, same as predicate device | | Yes | |
| **Software Platform and General Workflow** | Yes, with new and modified features:<br>-Select&GO workflow extension<br>-Eco Power Mode<br>-Extended Gradient Eco Mode<br>-System Startup Timer | | Yes | |

## 9. Nonclinical Tests

The following performance testing was conducted on the subject devices.

| Performance Test | Tested Hardware or Software | Source/Rationale for test |
|---|---|---|
| Sample clinical images | new coil, new features and modified features in the pulse sequence types | Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices |
| Image quality statement by U.S. board radiologist. | new coil | Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices |
| SNR and Image Uniformity | new coil | Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices |
| Surface Heating | new coil | Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices |
| 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

A clinical investigation report was submitted to provide data acquired from a clinical setting for the subject device MAGNETOM Free.Max. The primary objective of this clinical investigation was to evaluate the diagnostic image quality of MAGNETOM Free.Max in the dentomaxillofacial region of healthy volunteers and patients. Data collected from the study demonstrated the diagnostic image quality of the MR images of the dentomaxillofacial region was adequate in a clinical setting, as well as the safety of using MAGNETOM Free.Max.

Sample clinical images were provided 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 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 Free.Max and MAGNETOM Free.Star with software *syngo* MR XA80A 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 |
| 12-347 | Radiology | Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis | 60601-2-33 Edition 4.0 2022-08 | IEC |
| 5-125 | General I (QS/ RM) | Medical devices - Application of risk management to medical devices | 14971 Third Edition 2019-12 | ISO |
| 5-129 | General I (QS/ RM) | Medical devices - Part 1: Application of usability engineering to medical devices | 62366-1: 2015 + AMD1:2020 | ANSI AAMI IEC |
| 13-79 | Software/ Informatics | Medical device software - Software life cycle processes [Including Amendment 1 (2016)] | IEC 62304:2006 + AMD1:2015 | IEC |
| 12-232 | Radiology | Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices | MS 4-2010 | NEMA |
| 12-288 | Radiology | Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images | MS 9-2008 (R2020) | NEMA |
| 12-352 | Radiology | Digital Imaging and Communications in Medicine (DICOM) 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) | 10993-1:2018 | ISO |

## 12. Conclusion as to Substantial Equivalence

MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA80A have the same basic technological characteristics as the predicate device systems, MAGNETOM Free.Max and MAGNETOM Free.Star with *syngo* MR XA60A (Cleared with K231617 on November 9, 2023), with respect to the magnetic resonance features and functionalities. While there are some differences in technical features compared to the predicate devices, the differences have been tested and the conclusions from all verification and validation data suggest that the features bear an equivalent safety and performance profile to that of the predicate devices and reference devices.

Siemens believes that MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA80A are substantially equivalent to the currently marketed device MAGNETOM Free.Max and MAGNETOM Free.Star with *syngo* MR XA60A.