



December 19, 2025

Siemens Healthcare GmbH  
% Alina Goodman  
Regulatory Affairs Professional  
Siemens Medical Solutions USA, Inc.  
40 Liberty Boulevard  
Malvern, Pennsylvania 19355

Re: K252838

Trade/Device Name: MAGNETOM Sola; MAGNETOM Altea; MAGNETOM Sola Fit; MAGNETOM Viato.Mobile; MAGNETOM Vida; MAGNETOM Lumina; MAGNETOM Vida Fit; MAGNETOM Flow.Elite; MAGNETOM Flow.Neo; MAGNETOM Flow.Rise

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: Class II

Product Code: LNH, LNI, MOS

Dated: November 20, 2025

Received: November 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read 'DK', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

Daniel M. Krainak, PhD  
Assistant Director  
DHT8C: Division of Radiological  
Imaging and Radiation Therapy Devices  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K252838

Device Name

MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit, MAGNETOM Viato.Mobile, MAGNETOM Vida, MAGNETOM Lumina, MAGNETOM Vida Fit, MAGNETOM Flow.Neo, MAGNETOM Flow.Elite, MAGNETOM Flow.Rise

Indications for Use (Describe)

Indications for Use for MAGNETOM Vida, MAGNETOM Lumina, MAGNETOM Vida Fit, MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit, MAGNETOM Viato.Mobile:

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.

Indications for Use for MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise:

The MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays, depending on optional local coils that have been configured with the system, the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:** September 29, 2025

**Manufacturer:** Siemens Healthineers AG  
Magnetic Resonance (MR)  
Allee am Röthelheimpark 2  
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  
Regulatory Affairs Professional  
Siemens Medical Solutions USA, Inc.  
40 Liberty Boulevard  
Malvern, PA 19355, USA  
Phone: +1(317)371-8593  
E-mail: [alina.goodman@siemens-healthineers.com](mailto:alina.goodman@siemens-healthineers.com)

## 3. Device Name and Classification

**Device/ Trade name:** MAGNETOM Vida  
**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 Lumina

**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 Vida Fit  
**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 Sola  
**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 Altea  
**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 Sola Fit  
**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 Viato.Mobile  
**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 Flow.Elite  
**Classification Name:** Magnetic Resonance Diagnostic Device (MRDD)  
**Classification Panel:** Radiology  
**CFR Code:** 21 CFR § 892.1000

<b>Classification:</b>	II
<b>Product Code:</b>	Primary: LNH Secondary: LNI, MOS
<b>Device/ Trade name:</b>	MAGNETOM Flow.Neo
<b>Classification Name:</b>	Magnetic Resonance Diagnostic Device (MRDD)
<b>Classification Panel:</b>	Radiology
<b>CFR Code:</b>	21 CFR § 892.1000
<b>Classification:</b>	II
<b>Product Code:</b>	Primary: LNH Secondary: LNI, MOS
<b>Device/ Trade name:</b>	MAGNETOM Flow.Rise
<b>Classification Name:</b>	Magnetic Resonance Diagnostic Device (MRDD)
<b>Classification Panel:</b>	Radiology
<b>CFR Code:</b>	21 CFR § 892.1000
<b>Classification:</b>	II
<b>Product Code:</b>	Primary: LNH Secondary: LNI, MOS

#### 4. Legally Marketed Predicate and Reference Device

##### 4.1. Predicate Device

<b>Trade name:</b>	MAGNETOM Vida
<b>510(k) Number:</b>	K231560
<b>Classification Name:</b>	Magnetic Resonance Diagnostic Device (MRDD)
<b>Classification Panel:</b>	Radiology
<b>CFR Code:</b>	21 CFR § 892.1000
<b>Classification:</b>	II
<b>Product Code:</b>	Primary: LNH Secondary: LNI, MOS
<b>Trade name:</b>	MAGNETOM Lumina
<b>510(k) Number:</b>	K231560
<b>Classification Name:</b>	Magnetic Resonance Diagnostic Device (MRDD)
<b>Classification Panel:</b>	Radiology
<b>CFR Code:</b>	21 CFR § 892.1000
<b>Classification:</b>	II
<b>Product Code:</b>	Primary: LNH Secondary: LNI, MOS
<b>Trade name:</b>	MAGNETOM Sola
<b>510(k) Number:</b>	K232535
<b>Classification Name:</b>	Magnetic Resonance Diagnostic Device (MRDD)
<b>Classification Panel:</b>	Radiology
<b>CFR Code:</b>	21 CFR § 892.1000
<b>Classification:</b>	II
<b>Product Code:</b>	Primary: LNH Secondary: LNI, MOS

**Trade name:** MAGNETOM Altea  
**510(k) Number:** K232535  
**Classification Name:** Magnetic Resonance Diagnostic Device (MRDD)  
**Classification Panel:** Radiology  
**CFR Code:** 21 CFR § 892.1000  
**Classification:** II  
**Product Code:** Primary: LNH  
 Secondary: LNI, MOS

**Trade name:** MAGNETOM Viato.Mobile  
**510(k) Number:** K250443  
**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 Sola Fit  
**510(k) Number:** K250443  
**Classification Name:** Magnetic Resonance Diagnostic Device (MRDD)  
**Classification Panel:** Radiology  
**CFR Code:** 21 CFR § 892.1000  
**Classification:** II  
**Product Code:** Primary: LNH  
 Secondary: LNI, MOS

#### 4.2. Reference Device

**Trade name:** MAGNETOM Vida Fit  
**510(k) Number:** K220939  
**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 Flow.Ace  
**510(k) Number:** K250436  
**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 Skyra Fit  
**510(k) Number:** K250443  
**Classification Name:** Magnetic Resonance Diagnostic Device (MRDD)  
**Classification Panel:** Radiology



<b>CFR Code:</b>	21 CFR § 892.1000
<b>Classification:</b>	II
<b>Product Code:</b>	Primary: LNH Secondary: LNI, MOS
<b>Trade name:</b>	MAGNETOM Free.Max
<b>510(k) Number:</b>	K231617
<b>Classification Name:</b>	Magnetic Resonance Diagnostic Device (MRDD)
<b>Classification Panel:</b>	Radiology
<b>CFR Code:</b>	21 CFR § 892.1000
<b>Classification:</b>	II
<b>Product Code:</b>	Primary: LNH Secondary: MOS
<b>Trade name:</b>	syngo.via VB40A
<b>510(k) Number:</b>	K191040
<b>Product Code:</b>	Primary: LLZ

## 5. Intended Use / Indications for Use

Indications for Use for MAGNETOM Vida, MAGNETOM Lumina, MAGNETOM Vida Fit, MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit, MAGNETOM Viato.Mobile:

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.

Indications for Use for MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise:

The MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays, depending on optional local coils that have been configured with the system, the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

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

## 6. Device Description

The subject device, **MAGNETOM Vida with software Syngo MR XB10**, consists of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Vida with syngo MR XA60A (K231560).

A high-level summary of the new and modified hardware and software is provided below:

### **New Hardware:**

- myExam 3D Camera
- BM Contour XL Coil

### **Modified Hardware:**

- RF Transmitter TBX3 3T (TX Box 3)
- MaRS (Measurement and reconstruction system)

### **Software**

#### **New Features and Applications:**

- Brachytherapy Support for use with MR conditional applicators
- CS Vibe
- myExam Implant Suite
- DANTE blood suppression
- SMS Averaging for TSE
- SMS Averaging for TSE\_DIXON
- SMS for BLADE without diffusion function
- BioMatrix Motion Sensor
- RF pulse optimization with VERSE
- Deep Resolve Boost for FL3D\_VIBE and SPACE
- Deep Resolve Sharp for FL3D\_VIBE and SPACE
- ASNR recommended protocols for imaging of ARIA
- Preview functionality for Deep Resolve Boost
- EP2D\_FID\_PHS
- EP\_SEG\_FID\_PHS
- 3D Whole Heart
- Ghost reduction (Dual polarity Grappa (DPG))
- Fleet Reference Scan
- AutoMate Cardiac (Cardiac AI Scan Companion)
- Complex Averaging
- myExam Autopilot Spine
- myExam Autopilot Brain and myExam Autopilot Knee
- Open Workflow

#### **Modified features and applications:**

- GRE\_PC
- myExam RT Assist workflow improvements
- Open Recon 2.0

- Deep Resolve Boost for TSE
- "MTC Mode" for SPACE
- SPACE Improvement: high bandwidth IR pulse
- SPACE Improvement: increase gradient spoiling

The subject device, **MAGNETOM Lumina with software Syngo MR XB10**, consists of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Lumina with syngo MR XA60A (K231560). A high-level summary of the new and modified hardware and software is provided below:

**New Hardware:**

- myExam 3D Camera
- BM Contour XL Coil

**Modified Hardware:**

- RF Transmitter TBX3 3T (TX Box 3)
- MaRS (Measurement and reconstruction system)

**Software****New Features and Applications:**

- CS Vibe
- myExam Implant Suite
- DANTE blood suppression
- SMS Averaging for TSE
- SMS Averaging for TSE\_DIXON
- SMS for BLADE without diffusion function
- BioMatrix Motion Sensor
- RF pulse optimization with VERSE
- Deep Resolve Boost for FL3D\_VIBE and SPACE
- Deep Resolve Sharp for FL3D\_VIBE and SPACE
- Preview functionality for Deep Resolve Boost
- EP2D\_FID\_PHS
- EP\_SEG\_FID\_PHS
- Ghost reduction (Dual polarity Grappa (DPG))
- Fleet Reference Scan
- AutoMate Cardiac (Cardiac AI Scan Companion)
- Complex Averaging
- myExam Autopilot Spine
- myExam Autopilot Brain and myExam Autopilot Knee
- Compressed Sensing Cardiac Cine
- Open Workflow

**Modified Features and Applications:**

- GRE\_PC
- Open Recon 2.0
- Deep Resolve Boost for TSE
- "MTC Mode" for SPACE

- SPACE Improvement: high bandwidth IR pulse
- SPACE Improvement: increase gradient spoiling

**The subject device, MAGNETOM Vida Fit** with software Syngo MR XB10, consists of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Vida with syngo MR XA60A (K231560).

A high-level summary of the new and modified hardware and software is provided below:

**New Hardware:**

- myExam 3D Camera
- Beat Sensor
- BM Contour XL Coil

**Modified Hardware:**

- RF Transmitter TBX3 3T (TX Box 3)
- MaRS (Measurement and reconstruction system)
- Host computers

**Software**

**New Features and Applications:**

- Brachytherapy Support for use with MR conditional applicators
- CS Vibe
- myExam Implant Suite
- DANTE blood suppression
- SMS Averaging for TSE
- SMS Averaging for TSE\_DIXON
- SMS for BLADE without diffusion function
- BioMatrix Motion Sensor
- RF pulse optimization with VERSE
- Deep Resolve Boost for FL3D\_VIBE and SPACE
- Deep Resolve Sharp for FL3D\_VIBE and SPACE
- ASNR recommended protocols for imaging of ARIA
- Preview functionality for Deep Resolve Boost
- EP2D\_FID\_PHS
- EP\_SEG\_FID\_PHS
- GRE\_PC
- Open Recon 2.0
- 3D Whole Heart
- Ghost reduction (Dual polarity Grappa (DPG))
- Fleet Reference Scan
- AutoMate Cardiac (Cardiac AI Scan Companion)
- myExam Autopilot Spine
- myExam Autopilot Brain and myExam Autopilot Knee
- Deep Resolve for EPI
- Deep Resolve for HASTE
- Physiologging

- Complex Averaging
- Open Workflow

**Modified features and applications:**

- myExam RT Assist workflow improvements
- Deep Resolve Boost for TSE
- "MTC Mode" for SPACE
- myExam Angio Advanced Assist (Test Bolus)
- SPACE Improvement: high bandwidth IR pulse
- SPACE Improvement: increase gradient spoiling

The subject device, **MAGNETOM Sola with software Syngo MR XB10**, consists of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Sola with syngo MR XA61A (K232535).

A high-level summary of the new and modified hardware and software is provided below:

**New Hardware:**

- BM Contour XL Coil

**Modified Hardware:**

- MaRS (Measurement and reconstruction system)

**Software****New Features and Applications:**

- Brachytherapy Support for use with MR conditional applicators
- CS Vibe
- DANTE blood suppression
- BioMatrix Motion Sensor
- SPAIR FatSat Improvements: SPAIR "Abdomen&Pelvis" mode and SPAIR Breast mode
- RF pulse optimization with VERSE
- Deep Resolve Boost for FL3D\_VIBE and SPACE
- Deep Resolve Sharp for FL3D\_VIBE and SPACE
- ASNR recommended protocols for imaging of ARIA
- Preview functionality for Deep Resolve Boost
- EP2D\_FID\_PHS
- EP\_SEG\_FID\_PHS
- 3D Whole Heart
- AutoMate Cardiac (Cardiac AI Scan Companion)
- SMS Averaging for TSE
- SMS Averaging for TSE\_DIXON
- SMS for BLADE without diffusion function
- Ghost reduction (Dual polarity Grappa (DPG))
- Fleet Reference Scan
- Deep Resolve Swift Brain
- myExam Autopilot Spine
- Open Workflow

**Modified features and applications:**

- myExam Implant Suite
- GRE\_PC
- myExam RT Assist workflow improvements
- Open Recon 2.0
- Deep Resolve Boost for TSE
- "MTC Mode" for SPACE
- SPACE Improvement: high bandwidth IR pulse
- SPACE Improvement: increase gradient spoiling

The subject device, **MAGNETOM Altea with software Syngo MR XB10**, consists of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Altea with syngo MR XA61A (K232535).

A high-level summary of the new and modified hardware and software is provided below:

**New Hardware:**

- BM Contour XL Coil

**Modified Hardware:**

- MaRS (Measurement and reconstruction system)

**Software****New Features and Applications:**

- CS Vibe
- DANTE blood suppression
- BioMatrix Motion Sensor
- SPAIR FatSat Improvements: SPAIR "Abdomen&Pelvis" mode and SPAIR Breast mode
- RF pulse optimization with VERSE
- Deep Resolve Boost for FL3D\_VIBE and SPACE
- Deep Resolve Sharp for FL3D\_VIBE and SPACE
- Preview functionality for Deep Resolve Boost
- EP2D\_FID\_PHS
- EP\_SEG\_FID\_PHS
- AutoMate Cardiac (Cardiac AI Scan Companion)
- SMS Averaging for TSE
- SMS Averaging for TSE\_DIXON
- SMS for BLADE without diffusion function
- Ghost reduction (Dual polarity Grappa (DPG))
- Fleet Reference Scan
- Deep Resolve Swift Brain
- myExam Autopilot Spine
- Compressed Sensing Cardiac Cine
- Open Workflow

**Modified features and applications:**

- myExam Implant Suite
- GRE\_PC

- myExam RT Assist workflow improvements
- Open Recon 2.0
- Deep Resolve Boost for TSE
- “MTC Mode” for SPACE
- SPACE Improvement: high bandwidth IR pulse
- SPACE Improvement: increase gradient spoiling

The subject device, **MAGNETOM Sola Fit with software Syngo MR XB10**, consists of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Sola Fit with syngo MR XA70A (K250443).

A high-level summary of the new and modified hardware and software is provided below:

**New Hardware:**

- BM Contour XL Coil

**Modified Hardware:**

- MaRS (Measurement and reconstruction system)
- Host computers

**Software**

**New Features and Applications:**

- Brachytherapy Support for use with MR conditional applicators
- CS Vibe
- DANTE blood suppression
- BioMatrix Motion Sensor
- SPAIR FatSat Improvements: SPAIR “Abdomen&Pelvis” mode and SPAIR Breast mode
- RF pulse optimization with VERSE
- Deep Resolve Boost for FL3D\_VIBE and SPACE
- Deep Resolve Sharp for FL3D\_VIBE and SPACE
- ASNR recommended protocols for imaging of ARIA
- Preview functionality for Deep Resolve Boost
- EP2D\_FID\_PHS
- EP\_SEG\_FID\_PHS
- myExam Implant Suite
- GRE\_PC
- Open Recon 2.0
- SMS Averaging for TSE
- SMS Averaging for TSE\_DIXON
- SMS for BLADE without diffusion function
- Deep Resolve Swift Brain
- myExam Autopilot Spine
- Open Workflow

**Modified features and applications:**

- myExam RT Assist workflow improvements
- myExam Implant Suite
- Deep Resolve Boost for TSE

- “MTC Mode” for SPACE

The subject device, MAGNETOM Viato.Mobile with software Syngo MR XB10, consists of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Viato.Mobile with syngo MR XA70A (K250443).

A high-level summary of the new and modified hardware and software is provided below:

**New Hardware:**

- BM Contour XL Coil

**Modified Hardware:**

- MaRS (Measurement and reconstruction system)
- Host computers

**Software**

**New Features and Applications:**

- CS Vibe
- DANTE blood suppression
- BioMatrix Motion Sensor
- SPAIR FatSat Improvements: SPAIR “Abdomen&Pelvis” mode and SPAIR Breast mode
- RF pulse optimization with VERSE
- Deep Resolve Boost for FL3D\_VIBE and SPACE
- Deep Resolve Sharp for FL3D\_VIBE and SPACE
- ASNR recommended protocols for imaging of ARIA
- Preview functionality for Deep Resolve Boost
- EP2D\_FID\_PHS
- EP\_SEG\_FID\_PHS
- myExam Implant Suite
- GRE\_PC
- Open Recon 2.0
- SMS Averaging for TSE
- SMS Averaging for TSE\_DIXON
- SMS for BLADE without diffusion function
- Deep Resolve Swift Brain
- myExam Autopilot Spine
- Open Workflow

**Modified features and applications:**

- myExam Implant Suite
- Deep Resolve Boost for TSE
- “MTC Mode” for SPACE

With the subject software version, Syngo MR XB10, we are also introducing the following **new 1.5T devices**, which are part of our **MAGNETOM Flow. Platform**:

MAGNETOM Flow.Elite

MAGNETOM Flow.Neo

MAGNETOM Flow.Rise



The subject device, **MAGNETOM Flow.Elite, MAGNETOM Flow.Neo and MAGNETOM Flow.Rise with software Syngo MR XB10**, consists of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Sola with syngo MR XA61A (K232535).

A high-level summary of the new and modified hardware and software is provided below:

**New Hardware:**

- Magnet
- MREF (Magnet Refrigerator)
- Gradient system
- Gradient Coil
- RF System
- System Cover
- Patient Table
- MaRS (Measurement and Reconstruction System)
- Select&GO Display (TPAN\_3G) and Control Panel (CPAN\_2G)
- Body Coil
- Head/Neck Coil
- BM Head/Neck Coil (with ComfortSound)
- BM Contour S Coil
- BM Contour M Coil
- BM Contour L Coil
- BM Contour XL Coil
- Foot/Ankle Coil
- BM Spine Coil
- iTx Extremity 18 Flare
- Multi-Index MR-RT Positioning (a part of "RT Pro Edition" marketing bundle) (not available for MAGNETOM Flow.Rise)

**Modified Hardware:**

- Gradient Power Amplifier (GPA)
- SAR Monitoring
- In-Vivo Shim

**Software****New Features and Applications:**

- CS Vibe
- BioMatrix Motion Sensor
- SPAIR FatSat Improvements: SPAIR "Abdomen&Pelvis" mode and SPAIR Breast mode
- Deep Resolve Boost for FL3D\_VIBE and SPACE
- Deep Resolve Sharp for FL3D\_VIBE and SPACE
- Preview functionality for Deep Resolve Boost
- EP2D\_FID\_PHS
- EP\_SEG\_FID\_PHS
- AutoMate Cardiac (Cardiac AI Scan Companion)
- DANTE blood suppression

- SMS Averaging for TSE
- SMS Averaging for TSE\_DIXON
- SMS for BLADE without diffusion function
- Ghost reduction (Dual polarity Grappa (DPG))
- Fleet Reference Scan
- Deep Resolve Swift Brain
- Quick Protocols
- myExam Autopilot Spine
- Open Workflow

**Modified features and applications:**

- myExam Implant Suite
- GRE\_PC
- myExam RT Assist workflow improvements (not available for MAGNETOM Flow.Rise)
- Open Recon 2.0
- Deep Resolve Boost for TSE
- "MTC Mode" for SPACE
- SPACE Improvement: high bandwidth IR pulse
- SPACE Improvement: increase gradient spoiling

**New (general) Software / Platform / Workflow:**

- Select&GO extension (coil-based Iso Centering, Patient Registration at the touch display, Start Scan at the touch display)
- New Startup-Timer
- myExam RT Assist (not available for MAGNETOM Flow.Rise)
- myExam Brain RT-Autopilot (not available for MAGNETOM Flow.Rise)
- Eco Power Mode Pro

**Modified (general) Software / Platform:**

- Improved Gradient ECO Mode Settings

Furthermore, the following minor updates and changes were conducted for the subject devices MAGNETOM Vida, MAGNETOM Lumina, MAGNETOM Vida Fit, MAGNETOM Sola, MAGNETOM Altea:

- Off-Center Planning Support
- Flip Angle Optimization (Lock TR and FA)
- Inline Image Filter
- Automatic System Shutdown (ASS) sensor (Smoke Detector)
- ID Gain (re-naming)
- Select&Go Display (Touch Display (TPAN))
- Marketing bundle "myExam Companion"

The following minor updates and changes were conducted for the subject devices MAGNETOM Sola Fit and MAGNETOM Viato.Mobile:

- Off-Center Planning Support
- Automatic System Shutdown (ASS) sensor (Smoke Detector)
- ID Gain (re-naming)

- Select&Go Display (Touch Display (TPAN))
- Marketing bundle “myExam Companion”

The following minor updates and changes were conducted for the subject devices MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise:

- Off-Center Planning Support
- Flip Angle Optimization (Lock TR and FA)
- Inline Image Filter
- Automatic System Shutdown (ASS) sensor (Smoke Detector)
- ID Gain (re-naming)
- Marketing bundle “myExam Companion”
- Marketing Bundle “RT Pro Edition”(not available for MAGNETOM Flow.Rise)

## 7. Substantial Equivalence

MAGNETOM Vida, MAGNETOM Lumina, MAGNETOM Vida Fit, MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit, MAGNETOM Viato.Mobile, MAGNETOM Flow.Elite, MAGNETOM Flow.Neo and MAGNETOM Flow.Rise with software Syngo MR XB10 are substantially equivalent to the following devices:

Predicate Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with <i>syngo</i> MR XA60A	K231560, cleared on October 23, 2023	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Lumina with <i>syngo</i> MR XA60A	K231560, cleared on October 23, 2023	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Sola with <i>syngo</i> MR XA61A	K232535, cleared on December 22, 2023	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Altea with <i>syngo</i> MR XA61A	K232535, cleared on December 22, 2023	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Viato.Mobile with <i>syngo</i> MR XA70A	K250443, cleared on June 16, 2024	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Sola Fit with <i>syngo</i> MR XA70A	K250443, cleared on June 16, 2024	LNH, LNI, MOS	Siemens Healthcare GmbH

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Flow.Ace with <i>syngo</i> MR XA70A	K250436, cleared on June 16, 2024	LNH, LNI, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Free.Max with <i>syngo</i> MR XA60A	K231617, cleared on September 11, 2023	LNH, MOS	Siemens Shenzhen Magnetic Resonance

			Ltd.
MAGNETOM Skyra Fit with <i>syngo</i> MR XA70A	K250443, cleared on June 16, 2024	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Vida Fit with <i>syngo</i> MR XA50A	K220939, cleared on April 29, 2022	LNH, LNI, MOS	Siemens Healthcare GmbH
<i>syngo.via</i> VB40A	K191040	LLZ	Siemens Healthcare GmbH

## 8. Technological Characteristics

The subject devices, MAGNETOM Flow.Elite, MAGNETOM Flow.Neo, MAGNETOM Flow.Rise, MAGNETOM Vida, MAGNETOM Lumina, MAGNETOM Vida Fit, MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit, MAGNETOM Viato.Mobile, with software Syngo MR XB10, 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.

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
Software verification and validation	New or modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Sample clinical images	Coils, new or modified software features	Guidance for submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Image quality assessment by sample clinical images	- new / modified pulse sequence types. - comparison images between the new / modified features and the predicate device features	
Performance bench test	New and modified hardware	
Biocompatibility	surface of applied parts	ISO 10993-1
Electrical safety and electromagnetic compatibility (EMC)	Complete systems MAGNETOM Flow. Platform	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 new AI features in the subject devices.

### - Deep Resolve Swift Brain:

Test result summary	<p>The impact of the network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR), structural similarity index (SSIM) and normalized mean squared error (NMSE). Additionally, images were inspected visually to ensure that potential artefacts are detected that are not well captured by the metrics.</p> <p>After successful passing of the quality metrics tests, work-in-progress packages of the network were delivered and evaluated in clinical settings with collaboration partners.</p>
Test setup	<p><u>Equipment</u>: 3T and 1.5T MRI scanners.</p> <p><u>Protocols</u>: representative protocols (T1, T2*, T2, T2 FLAIR).</p> <p><u>Body region</u>: brain.</p> <p><u>Sample size</u>: 29,740 2D slices.</p> <p><u>Sample source</u>: in-house measurement.</p> <p>Note: Due to the network architecture, attributes like gender, age and ethnicity are not relevant to the training data.</p> <p><u>Dataset split</u>:</p> <p><u>Training</u>: 20,076 slices</p> <p><u>Validation</u>: 1.5T Validation: 3,616 slices (1.5T validation); 3T Validation: 6,048 slices (3T validation).</p> <p>Note: Data split maintained similar data distribution (e.g. contrast, orientation, field strength, ...) in both training and validation datasets.</p>
Patient Characteristics	No clinical subgroups have been defined for the datasets.
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 Gaussian noise to k-space data and uniformly-random cropping of the training data along the readout direction.
Data independency	Datasets for training and testing were split prior to training (see Test Setup field above).

### - Deep Resolve Boost for FL3D\_VIBE and Deep Resolve Boost for SPACE:

Test result summary	<p>Quantitative evaluations of structural similarity index (SSIM), peak signal-to-noise ratio (PSNR) and mean squared error (MSE) metrics showed a convergence of the training and improvements compared to conventional parallel imaging. An inspection of the test images did not reveal any negative impact to the image quality. The function has been used either to acquire images faster or to improve image quality.</p>
Test setup	<p><u>Equipment</u>: 0.55T, 1.5T and 3T scanners</p>

	<p><u>Protocols</u>: representative measurement protocols (T1, T2 and PD with and without fat saturation) which have been altered for training (e.g. to increase SNR, increase resolution or reduce acceleration).</p> <p><u>Body regions</u>: broad range of body regions</p> <p><u>Used coils</u>: broad range of coils to cover the dedicated body regions</p> <p><u>Sample size</u>: 27,679 3D patches from 1265 measurements</p> <p><u>Dataset split</u>: Training: 81% of the 1265 measurements Validation: 19% of the 1265 measurements</p> <p>Note: Data split maintained similar data distribution (e.g., contrast, orientation, field strength, ...) in both training and validation datasets.</p> <p><u>Sample source</u>: in-house measurements (training and validation) and collaboration partners (testing)</p>
Patient Characteristics	<p><u>Gender distribution</u>:</p> <ul style="list-style-type: none"> <li>- Male: 53%</li> <li>- Female 47%</li> </ul> <p><u>Age</u>: for training and validation.</p> <ul style="list-style-type: none"> <li>- 19 - 45: 14%</li> <li>- 46 - 65: 43%</li> <li>- 66 - 89: 43%</li> </ul> <p><u>Clinical subgroups</u>: No clinical subgroups have been defined for the datasets.</p>
Reference standard	The acquired datasets (as described above) represent the ground truth for the training and validation. Input data was retrospectively created from the ground truth by data manipulation and augmentation. This process includes further undersampling of the data by discarding k-space lines as well as creating sub-volumes of the acquired data.
Data independency	Datasets determined for training and validation were split prior to training along individual acquisitions to ensure that there is no mixture of sub-volumes stemming from the same acquisition.

**- Deep Resolve Sharp for FL3D\_VIBE and Deep Resolve Sharp for SPACE**

Test result summary	The impact of the Deep Resolve Sharp network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR), structural similarity index (SSIM), and perceptual loss. The tests include 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 and reduced Gibb's artifacts.
Test setup	<p><u>Equipment</u>: 0.55T, 1.5T and 3T MRI scanners</p> <p><u>Protocols</u>: representative measurement protocols (T1, T2 and PD with and without fat saturation) which have been altered (e.g. to increase SNR, increase resolution or reduce acceleration)</p> <p><u>Body regions</u>: broad range of different body regions.</p> <p><u>Used coils</u>: broad range of coils to cover the dedicated body regions</p> <p><u>Sample size</u>: approx. 13,000 high resolution 3D patches from 500 measurements.</p> <p><u>Dataset split</u>: Training: 70% of the 500 measurements.</p>

	<p>Validation: 30% of the 500 measurements</p> <p>Note: Data split maintained similar data distribution (e.g., contrast, orientation, field strength, ...) in both training and validation datasets.</p> <p><u>Sample source:</u> in-house measurements</p>
Patient Characteristics	<p><u>Gender distribution:</u></p> <ul style="list-style-type: none"> <li>- Male: 66.6%</li> <li>- Female 33.4%</li> </ul> <p><u>Age:</u> for training and validation.</p> <ul style="list-style-type: none"> <li>- 19 - 45: 8.4%</li> <li>- 46 - 65: 40.2%</li> <li>- 66 - 89: 51.4%</li> </ul> <p><u>Clinical subgroups:</u> No clinical subgroups have been defined for the datasets.</p>
Reference standard	<p>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.</p>
Data independency	<p>The high-resolution datasets were split to 70% training and 30% validation datasets before training to ensure independence of them. The input and output variables of the network have been derived from the same dataset so that no confounders exist for the training methodology.</p>

#### - Deep Resolve Boost for TSE

Test result summary	<p>The evaluation on the test dataset confirmed very similar metrics in terms of peak signal-to-noise ratio (PSNR), structural similarity index (SSIM) and learned perceptual image patch similarity metrics (LPIPS) for the predicate and the modified network with both outperforming conventional GRAPPA as the reference. Visual evaluations confirmed statistically significant reduction of banding artifacts with no significant changes in sharpness and detail visibility. In addition, the radiologist evaluation revealed no difference in suitability for clinical diagnostics between updated and cleared predicate network.</p> <p>The function as on the predicate devices was modified to the subject devices but the training and testing from the predicate devices still fits.</p>
Test setup	<p><u>Equipment:</u> 0.55T, 1.5T and 3T MRI scanners</p> <p><u>Protocols:</u> representative protocols (T1, T2 and PD with and without fat saturation)</p> <p><u>Body regions:</u> broad range of different body regions</p> <p><u>Used coils:</u> broad range of coils to cover the dedicated body regions</p> <p>Testing of the Deep Resolve Boost network has been described in the reference and predicate device submissions. Additional tests have been performed to evaluate the banding artifact reduction capabilities of the updated network.</p> <p><u>Dataset split:</u> Training: more than 23250 slices (93%)</p>

	<p>Validation: more than 1750 slices (7%) Additional test dataset for banding artifact reduction: more than 2000 slices</p> <p>For training and validation of the network, the identical data was used as for the initial device submission (K213693).</p> <p>Note: Data split maintained similar data distribution (e.g., contrast, orientation, field strength, ...) in both training and validation datasets.</p> <p>Sample source: in-house measurements and collaboration partners</p>
Patient Characteristics	<p>Due to reasons of data privacy, gender, age and ethnicity during data collection have not been recorded. Due to the network architecture, attributes like gender, age and ethnicity are not relevant to the training data.</p> <p>No clinical subgroups have been defined for the collected dataset</p>
Reference standard	<p>The acquired training/validation datasets (identical to the initial submission K213693) 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 undersampling of the data by discarding k-space lines, lowering of the SNR level by addition of noise and mirroring of k-space data.</p>
Data independency	<p>Training and validation datasets were kept independent from each other during training and validation. The acquired datasets (one dataset consists of a group of multiple slices) were split into 93% training and 7% validation data prior to the training. A similar distribution was maintained for training and validation data. The test dataset for banding artifact reduction was acquired after the release of the predicate network and is therefore independent of the training/validation data.</p>

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

## 10. Clinical Tests

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

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 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.

The subject devices with Syngo MR XB10 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 (IEC 60601-1:2005, MOD)	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	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)	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	ANSI AAMI ISO

## **12. Conclusion as to Substantial Equivalence**

MAGNETOM Flow.Neo, MAGNETOM Flow.Elite, MAGNETOM Flow.Rise, MAGNETOM Vida, MAGNETOM Lumina, MAGNETOM Vida Fit, MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit, MAGNETOM Viato.Mobile, with software Syngo MR XB10 have the same intended use and same basic technological characteristics than the respective predicate devices, 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 device and reference devices.

Siemens believes that the subject devices MAGNETOM Flow.Neo, MAGNETOM Flow.Elite, MAGNETOM Flow.Rise, MAGNETOM Vida, MAGNETOM Lumina, MAGNETOM Vida Fit, MAGNETOM Sola, MAGNETOM Altea, MAGNETOM Sola Fit, MAGNETOM Viato.Mobile, with software Syngo MR XB10 are substantially equivalent to the currently marketed devices MAGNETOM Vida and MAGNETOM Lumina with syngo MR XA60A (K231560, cleared on October 23, 2023), MAGNETOM Sola and MAGNETOM Altea with syngo MR XA61A (K232535, cleared on December 22, 2023) and MAGNETOM Sola Fit and MAGNETOM Viato.Mobile with syngo MR XA70A (K250443, cleared on June 16, 2024).