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Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact Office of Health Technology 8 (OHT8): Office of Radiological Health at RadHealth@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Public Comment

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance document provides a detailed description of the information that should be included in a premarket notification for a magnetic resonance diagnostic device (MRDD). This document is intended to be used in conjunction with information regarding the content and format of a 510(k) premarket notification[1]. The approach outlined in this guidance document is intended to facilitate the timely review and marketing clearance of MRDDs.

The guidance reflects an update to harmonize with the 4th edition of the FDA recognized standard IEC 60601-2-33 *Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*. In the 4th edition of IEC 60601-2-33, the main magnetic field (B0) hazard area was re-defined as anywhere where the magnetic field is equal to or greater than 0.9 mT as the space around MR equipment where the static magnetic field can cause harm. Prior versions of IEC 60601-2-33 had defined this controlled access area as 0.5 mT. For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] If submitting a Declaration of Conformity to a recognized standard, we recommend you include the appropriate supporting documentation. For more information regarding use of consensus standards in

[1] Refer to FDA guidance titled "Electronic Submission Template for Medical Device 510(k) Submissions", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions

[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

regulatory submissions, refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[3]

MRDDs are also electronic products under section 531(2) of Subchapter C (Electronic Product Radiation Control (EPRC)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). As such, MRDDs are subject to the radiological health requirements in Title 21, Subchapter J, Parts 1000 through 1050 of the Code of Federal Regulations, including applicability of general and specific performance standards (21 CFR Parts 1010-1050) and other general requirements for reporting and recordkeeping (21 CFR Part 1002), notification and corrective actions for defective or non-compliant electronic products (21 CFR Parts 1003 and 1004), and importation (21 CFR Part 1005).

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. Scope

This document is applicable to MRDDs as defined in 21 CFR 892.1000:

> **21 CFR 892.1000: Magnetic resonance diagnostic device.**
>
> (a) *Identification*. A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).
>
> (b) *Classification*. Class II.

MRDDs are Class II medical devices that require premarket notification and an agency determination of substantial equivalence prior to marketing. Three product codes are currently used to identify these devices:

LNH – Nuclear Magnetic Resonance Imaging System
LNI – Nuclear Magnetic Resonance Spectroscopic System
MOS - Magnetic Resonance Specialty Coil

The principal components of current MRDDs include the main magnet, shim and gradient systems, radiofrequency transmitter and receiver, transmit and receive coils, power supplies, computer and software, patient supports, and physiological gating devices.

[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

This guidance document is applicable to premarket notifications for magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS) systems, components, and accessories, and modifications to systems, components, and accessories, which could significantly affect the safety or effectiveness of the MRDD and trigger the need for premarket notification submission prior to marketing.

The information in this guidance document is also applicable to the MRI system components of dual-modality devices, such as PET/MRI systems.

III. Relevant Standards

Standards may be used only when applicable (section 514(c)(1)(A) of the FD&C Act); not all standards specified below are applicable to all MRDD 510(k) submissions.

A. NEMA Standards

Standards promulgated by the National Electrical Manufacturers Association (NEMA) provide standardized test methods for the assessment of performance and safety parameters for MRDDs. The NEMA standards only prescribe standard measurement methods and do not specify acceptance criteria. You should define acceptance criteria for your device. FDA will evaluate acceptance criteria on a case-by-case basis depending on the intended use and specific technological characteristics of your device. NEMA test methods recognized by FDA include:

- MS 1 *Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images*
- MS 2 *Determination of Two-dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images*
- MS 3 *Determination of Image Uniformity in Diagnostic Magnetic Resonance Images*
- MS 4 *Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices*
- MS 5 *Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging*
- MS 6 *Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI)*
- MS 8 *Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems*
- MS 9 *Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images*
- MS 10 *Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging*
- MS 12 *Quantification and Mapping of Geometric Distortion for Special Applications*

B. IEC 60601-2-33

The International Electrotechnical Commission (IEC) standard, IEC 60601-2-33 *Medical Electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*, is the international standard for the safety of magnetic resonance equipment intended for medical diagnosis. IEC 60601-2-33 provides particular specifications for magnetic resonance diagnostic equipment and takes precedence over the specifications provided in the general IEC 60601 series.

The NEMA standards for measuring acoustic noise (NEMA MS 4) and SAR (NEMA MS 8) have been incorporated into IEC 60601-2-33. However, IEC 60601-2-33 does not address performance issues, such as SNR, image uniformity, geometric distortion and slice thickness.

C. Other Applicable Standards

- ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and Testing within a Risk Management Process*. This standard applies to patient-contacting materials in MRDDs.
- NEMA PS 3.1 - 3.20 *Digital Imaging and Communications in Medicine (DICOM)*. This standard specifies formats for the digital exchange of medical images.
- ANSI/AAMI ES60601-1 *Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* (- Note: This standard is recognized with relevant U.S. national differences applied)
- IEC 60601-1-2 *Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Disturbances - Requirements and tests*

IV. Describing Your Device in a 510(k) Premarket Notification

When submitting a 510(k) premarket notification for a MRDD, you must include the information required under 21 CFR 807.87. You should identify your device by regulation and product code and should also include the information below.

A. Indications for Use

You should describe with particularity, as described below, the Indications for Use (IFU) for your device. The device labeling, training materials, performance claims, promotional materials, and any other materials in the submission should all be consistent with the IFU.

Specific clinical indications (for example, disease identification or rule-out, diagnosis or prognosis with respect to disease staging or severity, and prevention or reduction in morbidity and/or mortality associated with particular diseases) are beyond the scope of this document. While the Agency handles each such application on an individual basis, the Agency believes that clinical studies are

often necessary to support such specific clinical indications. Prior to the submission of any such application, you are encouraged to contact the Agency to discuss the level of supporting evidence required and clinical trial study design. For information on FDA's Q-submission process, refer to FDA guidance titled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."[4]

MRDDs often contain protocols recommended for specific applications (for example, adult abdomen, pediatric brain, etc.). For MRDDs, these specific protocols do not necessarily create a new specific indication for the MRDD, provided that disease-specific or diagnostic claims are not made. For example, a "Pediatric Brain" protocol would be acceptable under a general IFU, but a "Pediatric Epilepsy Foci identification" protocol would likely be interpreted as a new specific indication.

The Indications for Use for radiofrequency (RF) coils and accessory devices should specify the MRI system(s) with which the devices are intended to be used. The level of detail necessary will depend upon the individual device and the MRI systems with which it is intended to be used. For example, FDA generally believes that specifying the manufacturer and field strength of the compatible MRI system is appropriate for an RF coil.

B. Device Description

You should provide a comprehensive description of your device in the premarket notification that includes the information below:

(1) Magnet

A full description of the main magnet including:

- Field strength and type of magnet (superconducting, resistive or permanent)
- Dimensions of the patient-accessible bore space
- Type of installation (fixed, mobile, interventional, or transportable)
- Design characteristics of the magnet, including weight, cryogens and boil-off rates (if applicable), bore dimensions, type of shielding, shimming method
- Performance characteristics of the magnet, including decay characteristics of the magnetic field in the event of a quench, fringe field maps (including 0.5 mT, 0.9 mT, 3 mT, 5 mT, 10 mT, 20 mT, 40 mT and 200 mT contours), stability of the field (ppm/hr) over a prolonged period of time, and spatial homogeneity (ppm/volume)

(2) Gradient System

A full description of the gradient system including:

- A dimensioned illustration of the gradient tube
- Information on shielding and cooling
- Maximum gradient amplitude (per axis) in T/m, rise time (ms), and maximum slew rate (T/m/s)

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

- A description of how cardiac and peripheral nerve stimulation control is implemented, including a discussion of any hardware or software mechanism to limit gradient output (dB/dt) for systems capable of exceeding the time rate of change of the magnetic field (dB/dt) of 20 T/s.

  If peripheral nerve stimulation (PNS) is possible, you should describe the level of gradient output at which the operator is notified. You should also include information about how the operator is informed that PNS is possible. Painful stimulation should be avoided.
- You should provide information about the operating modes implemented on the system (for example, Normal, First Level Controlled, Second Level Controlled) and how users navigate between the different modes.

(3) Radiofrequency System

You should provide a description of the architecture of the RF transmit-receive system, including the number of transmit and receive channels, amplifier peak power and duty cycle.

FDA recommends that all MRDDs retain the ability to operate in quadrature transmit mode. If applicable, you should include a description of how the user identifies and selects quadrature transmit mode on your system.

(4) RF Coils

For each RF coil included with your system, you should provide the following information:

- Type of coil (transmit, receive, transmit/receive)
- Description of the hardware characteristics of the coil (for example, geometry, materials, dimensions)
- A description of the coil design (for example, linear, quadrature, phased array, multi-channel transmit)
- Intended use (resonant nuclei, frequencies, anatomical region of interest)
- Schematic of the coil design including the location of individual coil elements
- Circuit diagrams
- A description of the decoupling method(s) employed (for receive-only coils)

(5) SAR Management and Control System

- A description of the SAR management and control system, including how whole-body averaged (avg-WB), partial body (PB), head-averaged, local (10g-averaged) SAR, and specific absorbed energy (i.e., SAR over the examination time) control is implemented
- Information about the operating modes implemented on the system and how users navigate between the different operating modes
- The specification for accuracy and uncertainty in the console-reported SAR values
- A description of how energy deposition information is communicated to the user
- You should explain all warnings or other feedback provided to the user

(6) Pulse Sequences

For purposes of this guidance, FDA uses the term “pulse sequence” to mean a technique like spin echo, gradient echo, echo planar imaging, etc., including their parameterization (for example echo

time, repetition time, number of slices). For each pulse sequence provided on your MRDD, you should provide the following:

- Pulse sequence diagram
- Pulse sequence type (for example spin echo, gradient echo, fast spin echo, 2D/3D)
- Contrast characteristics (for example, T1, T2, weighting, fat saturation)
- k-space trajectory (spiral, Cartesian, etc.)
- Associated options (shimming, parallel imaging, saturation pulses, etc.)
- Coil preference or limitations (if any)
- Additional accessory equipment required (for example, respiratory and/or cardiac gating, elastography drivers)
- Summary of image reconstruction method (for example FFT, compressed sensing)

(7) Imaging Protocols

For purposes of this guidance, FDA uses the term "imaging protocol" to mean a workflow tool consisting of multiple pulse sequences prescribed in a defined order. For each manufacturer-provided protocol, you should provide the information below.

- Target anatomy
- A list of the pulse sequences included in each protocol
- Coil preference or restriction (if any)
- Whether the protocol is intended to be used in combination with exogenous contrast media

(8) Image Processing

For purposes of this guidance, FDA uses the term "image processing" to mean algorithms operating on acquired image data. For the purposes of this guidance, FDA does not consider reconstruction algorithms to be "image processing." For each image processing feature offered with the MRDD, you should provide:

- Inputs, their data formats, and methods of input (for example, feed from other modules, manual input)
- Functional description of the algorithm(s)
- Level of user interaction (for example, automated, semi-automated and manual, whether results can be edited or need to be reviewed by the user)
- Outputs, their data formats, and how they are displayed

Software - In general, a 510(k) application should include software documentation consistent with a Basic Documentation Level as specified in the FDA guidance titled "Content of Premarket Submissions for Device Software Functions."[5] The actual Documentation Level for your device may vary based on the specifics of your device.

If the device meets the definition of a cyber device under section 524B(c) of the FD&C Act, cybersecurity documentation under section 524B(b) of the FD&C Act is required as a part of the premarket submission. For more information on this topic, refer to FDA guidance titled

[5] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions

"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"[6].

If your device includes off-the-shelf software, you should provide the additional information as recommended in the FDA guidance titled "Off-The-Shelf Software Use in Medical Devices" and FDA guidance titled "Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software."[7]

(9) Accessories

Your 510(k) submission should include a list of the accessories provided with the system (for example, physiological monitoring accessories such as EKG leads, pulse oximeters, respiratory and/or cardiac gating, elastography drivers, or patient positioners).

(10) Additional Information

- A description of the patient table including dimensions, positioning accuracy and maximum supported weight
- Information about patient communication equipment, such as the nurse call or "panic button"
- Information about recommended RF shielding and how the "Special Environment" specifications in IEC 60601-1-2 are implemented and how integrity is maintained during operation
- FDA encourages the adoption of the Fixed Parameter Option on your MRDD. If fixed parameter options (such as FPO:B) are implemented on your system, you should describe the implementation. For additional information on a Fixed Parameter Option, see IEC 60601-2-33.

V. Electrical, Mechanical, Structural, and Related System Safety

You should evaluate the safety aspects of your device according to the following FDA-recognized consensus standards:

- ANSI/AAMI ES60601-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- IEC 60601-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* (- Note: This standard is recognized with relevant U.S. national differences applied)
- IEC 60601-1-2 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests*

[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices

[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-networked-medical-devices-containing-shelf-ots-software

For additional information on providing EMC information in a premarket submission, please refer to the FDA guidance titled "Electromagnetic Compatibility (EMC) of Medical Devices"[8].

If your MRDD incorporates wireless technology for data communication meeting the IEC 60601-1-2 standard is insufficient to demonstrate that the wireless technology will not be susceptible to electromagnetic interferences and continue to perform as intended. For additional information, refer to the FDA guidance titled "Radio-Frequency Wireless Technology in Medical Devices"[9].

VI. Physical Laboratory Testing

To demonstrate the substantial equivalence of your MRDD, you should provide the performance testing specified below. A number of the tests specified below can be performed in accordance with FDA-recognized consensus standards.

Not all of the testing below is applicable to all accessories. You should perform testing of relevant characteristics that may affect safety and effectiveness.

A. Performance

To demonstrate the performance of your MRDD, you should include an assessment of image quality metrics (such as signal-to-noise ratio, geometric distortion, image uniformity, slice thickness, and spatial resolution), as well as spectroscopy performance. The measurement method used should be specified for all testing, including for the performance metrics outlined below:

(1) Imaging

- **Signal to Noise Ratio (SNR)** – The measured SNR value as well as pre-determined pass/fail acceptance criteria for all coils included in the scope of the submission.
- **Geometric Distortion** – Distortion measured in all three slice orientations (sagittal, coronal and transverse) as well as pre-determined pass/fail acceptance criteria.
- **Image Uniformity** – Image uniformity measurements and/or gray-scale uniformity maps, as well as pre-determined pass/fail acceptance criteria for all coils included in the scope of the submission.
- **Slice Thickness** – Full-width-half-maximum (FWHM) values as well as pre-determined pass/fail acceptance criteria.
- **Spatial Resolution** – High contrast spatial resolution of the system demonstrated using suitable phantoms for the clinical pulse sequence protocols using the smallest field of view (FOV).

[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices

[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff

- **Image contrast validation** – The image contrast behavior for new pulse sequences. For example, fat saturation pulse sequences should demonstrate adequate fat signal suppression in a phantom composed of fat and water.

(2) Spectroscopy

No standardized tests have been developed for magnetic resonance spectroscopy performance. FDA recommends the following performance testing for systems with spectroscopy scan protocols. All test results should be accompanied by a description of the test methods used, including the pulse sequences and coils utilized, and the geometry and composition of the phantoms. The target anatomical region and the RF hardware used should be specified. Phantom testing should include performance characteristic such as:

- **Spatial Localization Accuracy** – Comparison of desired and actual volume
- **Spectral Resolution** – Full-width-half-maximum of the water resonance using the clinical protocols (for example, single voxel or chemical shift imaging)
- **Signal to Noise Ratio** – Ratio of peak amplitude to standard deviation of background for key metabolites (for example, N-Acetyl aspartate or lactate)
- **Water suppression** – Ratio of area of water peak with and without suppression
- **Decoupling** – Comparison of SNR with and without decoupling
- **Spectral Data Processing** – Validation of spectral post-processing techniques

B. Safety

To demonstrate the safety of your MRDD, you should address acoustic noise, gradient-induced electric fields, RF energy deposition and biocompatibility and flammability of patient-contacting materials as outlined below.

(1) Acoustic Noise

You should measure the acoustic output of your system and specify the measurement method used (for example, maximum gradient acoustic noise or maximum clinical acoustic noise). You should report unweighted peak sound pressure level (Lpeak) and the time integral of the A-weighted sound pressure level ($L_A$eq).

(2) Gradient-induced Nerve Stimulation

For gradient systems capable of producing dB/dt greater than 20 T/s, you should conduct volunteer studies with a minimum of 11 subjects to determine the threshold value for mild and painful peripheral nerve stimulation. If painful stimulation can be induced in your system, you should also determine the threshold of painful stimulation and provide an explanation of how painful stimulation is avoided.

(3) RF Energy Deposition

For volume-transmit coils, you should measure whole-body averaged, head averaged, and/or partial body SAR values. You should specify the test method used (for example, pulse energy or calorimetry). You should report both the measured and the scanner-displayed SAR values and should specify the uncertainty boundaries for all reported SAR values.

For surface transmit coils, you should measure local 10g-averaged SAR values. You should report both the measured and the scanner-displayed SAR values and include uncertainty boundaries for all reported SAR values.

For multi-channel transmit coils, you should provide a discussion of how the peak local (10g-averaged) SAR values in your system compare to peak values in quadrature volume coils that conform to the current whole-body and whole-head IEC 60601-2-33 SAR limits. This discussion should encompass the entire patient population and anatomical scan landmarks for which your device is indicated. If computational models are used to support substantial equivalence, these models should be accompanied by validation and uncertainty data. You should include uncertainty boundaries for all reported SAR values.

(4) Surface Heating of RF Receive Coils

To ensure patient safety and prevent thermal injury to patients undergoing MR exams, you should measure the temperature rise of all receive-only coils included with the system. The results reported to FDA should include an assessment of why the measured temperature rise is acceptable and does not pose a risk to patients. FDA recommends that temperature be measured at locations in the coil pre-determined to be the local hot spots, and that you conduct this test for the coil in the normal operating condition, and for the single fault condition of the coil left in the bore of the magnet unplugged.

(5) Biocompatibility

You should address biocompatibility for any patient-contacting materials. For additional information, refer to FDA guidance titled "Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process""[10].

(6) Fixed parameter options

If fixed parameter options (such as FPO: B) are implemented on your system, you should demonstrate that your device operates within the FPO limits.

VII. Clinical Images

You should provide sample clinical images to support the ability of your system to generate diagnostic quality images.

For newly introduced systems, you should provide sample clinical images for all pulse sequences.

If a pulse sequence is employed in multiple clinical protocols, the sample clinical images should support the ability of the pulse sequence to achieve the desired contrast characteristics in those clinical protocols. Scientific rationale and a limited set of sample clinical images may be adequate to support the use of a pulse sequence across multiple protocols.

[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and

You should provide images to the Agency in electronic DICOM format. You should remove any patient identifiers prior to submitting images to FDA. FDA requests that all images be accompanied by a description of the target anatomical site, scan parameters employed, and the total imaging time.

In lieu of submitting the full set of sample clinical images to the Agency, you may provide a statement from a U.S. Board Certified radiologist attesting that images produced by the device are of sufficient quality for diagnostic use. A description of the sequences and anatomical regions reviewed by the radiologist should be provided. Any issues with image evaluation or image quality should be fully explained. In addition, you should provide a small, representative subset of clinical images.

VIII. Device Modifications

In accordance with 21 CFR 807.81(a)(3), a device change or modification "that could significantly affect the safety or effectiveness of the device" or represents "a major change or modification in the intended use of the device" requires a new 510(k).[11] The changes or modifications listed below are examples of changes that FDA believes may require submission of a new 510(k). Note that this list is not exhaustive but provides examples of modifications that will generally require submission of a new 510(k). For additional details, see FDA guidances "Deciding When to Submit a 510(k) for a Change to an Existing Device"[12] and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."[13]

- **Main Static Magnetic Field.** FDA considers a change in the main static magnetic field to be a significant change or modification in design and has determined that this change could significantly affect both the safety and effectiveness of the device by altering the system's resonant frequency. Thus, modifications to the main static magnetic field generally require a new 510(k). You should support this modification with testing for SNR, geometric distortion, and image uniformity (all measured over the system's maximum FOV). Additionally, you

[11] Section 3308 of the Food and Drug Omnibus Reform Act of 2022, FDORA added section 515C "Predetermined Change Control Plans for Devices" to the FD&C Act (Pub. L. No. 117-328). Under section 515C, FDA may under certain circumstances approve or clear a predetermined change control plan (PCCP) for a device that describes planned changes that may be made to a device and that would otherwise require a supplemental premarket approval application or a new premarket notification. For example, section 515C provides that a supplemental premarket approval application (section 515C(a)) or a new premarket notification (section 515C(b)) is not required for a change to a a previously approved or cleared device if the change is consistent with a PCCP that is approved or cleared by FDA. Section 515C also provides that FDA may require that a PCCP include labeling required for safe and effective use of the device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan. If you are interested in proposing a PCCP in your marketing submission, we encourage you to submit a Pre-Submission to engage in further discussion with CDRH. See FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

[12] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device

[13] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device

should also provide measurement of magnetic field homogeneity and stability of the field (ppm/hr) over a prolonged period of time.

- **Gradient System.** FDA considers a change to the gradient system to be a significant change or modification in the design of the device and has determined that this change could significantly affect both the safety and effectiveness of the MRI system by altering the PNS potential, slice selection efficacy, and acoustic output of the system. Thus, modifications to the gradient system generally require a new 510(k). Changes to the gradient system should be supported by measurement of geometric distortion and slice profile thickness (with a representative volume coil), as well as an assessment of the acoustic output of the system. Any changes to PNS control should also be provided.
- **RF Body Transmit Coil.** FDA considers a change to the integrated RF body transmit coil to be a significant modification in design and has determined that this change could significantly affect the safety and effectiveness of the system by modifying the RF energy output. Thus, modifications to the integrated RF body transmit coil generally require a new 510(k). Such modifications should be supported by testing for RF energy deposition, SNR, and image uniformity.
- **Other Transmit Coils.** Modifications to transmit coils other than the integrated RF body transmit coil may also require a 510(k) submission. Changes in coil transmit architecture are usually a significant change or modification in design that could significantly affect both the safety (e.g., heating) of the coil as well as effectiveness (e.g., image quality) of the MRI system. Thus, modifications to the coil transmit architecture generally require a new 510(k). The 510(k) should include testing for RF energy deposition, coil surface heating, biocompatibility (if patient contacting), SNR, and image uniformity. However, changes in material type, formulation, chemical composition, or material processing for non-patient contacting coil housing materials are unlikely to significantly affect safety and effectiveness, and thus, do not generally require a new 510(k) submission. When deciding whether a 510(k) is needed for modification of transmit coils, you should consider whether modifications have been made to the intended use, design, or technological characteristics of the device and the impact of such modifications.
- **RF Receive Coils.** FDA considers the introduction of a new RF receive-only coil to be a significant modification in design and has determined that this change could significantly affect the safety and effectiveness of the device by altering the performance of the system. Thus, the introduction of a new RF receive-only coil generally requires a new 510(k). Such a 510(k) submission should include testing for SNR, image uniformity, coil surface heating, and biocompatibility (if intended to contact the patient). Modification of existing RF receive-only coils may or may not require a 510(k) submission depending on the modifications being made. Changes in material type, formulation, chemical composition, or material processing for non-patient contacting coil housing materials are unlikely to affect safety and effectiveness of the device, and thus, such changes are unlikely to require a new 510(k).
- **Pulse Sequences.** The introduction of a new pulse sequence or a modification of a pulse sequence may or may not require a 510(k) submission. For example, introduction of a metal artifact reduction pulse sequence is usually a major change or modification in the intended use of the device that significantly affects safety or effectiveness. Thus, such modification would generally require a new 510(k). Performance data should include an assessment of SNR and appropriate contrast behavior, as well as data supporting the intended use of the

pulse sequence. Modifications of previously-cleared pulse sequences that do not affect intended use generally do not require a new 510(k) submission.

- **Protocols.** Modifications to protocols may or may not require a 510(k) submission. For example, the addition of a pediatric epilepsy foci identification protocol is generally considered a major change or modification in the intended use of the MRDD that significantly affects safety or effectiveness. Thus, such a modification would generally require a new 510(k). Factors that should be considered in determining whether a 510(k) is needed include changes to target anatomical area, desired contrast characteristics, coil restrictions, and contrast media requirements. Re-ordering of existing pulse sequences within an existing protocol would generally not require a new 510(k), as the intended use and technology generally remain unaltered.
- A new 510(k) is generally not required for the addition of a protocol to a new device model if the protocol has been cleared in another model manufactured by the same manufacturer, and has similar technological characteristics as the model in which the protocol has been cleared.

IX. Labeling

You must include in the 510(k) submission labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). For a MRDD, such labeling should include the following items:

A. RF Coil Labeling

The label on all RF coils (with the exception of the integrated body coil) should clearly identify the coil as either a transmit/receive or a receive-only coil.

B. Summary Specification Sheet

The Summary Specifications Sheet should provide a description of the system configuration and components and provide a summary of available applications. The Summary Specifications Sheet should include the following information:

(1) Magnet

Field strength and type of magnet (superconducting, resistive or permanent), patient-accessible bore size, type of installation (fixed, mobile, interventional, or transportable), design characteristics of the magnet, including weight, bore size, cryogens and boil-off rates (if applicable), type of shielding, shimming method, performance characteristics of the magnet, including decay characteristics of the magnetic field in the event of a quench (time from full field to 20mT), temporal field stability (ppm/hr), spatial homogeneity and information about maximum |B|, |grad|B||, and |B|.|grad|B|| in patient-accessible values

(2) Gradient System

Maximum gradient amplitude (per axis) in T/m, rise time (ms), slew rate (T/m/s), and information on shielding and cooling. Peak acoustic output (peak and A-weighted)

(3) RF Subsystem

Resonant frequencies, the number of transmit and receive channels, amplifier peak power and duty cycle. Operating modes employed on the system (Normal, First Level Controlled, Second Level Controlled)

(4) RF Coils

For each coil marketed with the system, the type of coil (transmit, receive, transmit/receive), coil design (for example, linear, quadrature, phased array, multi-transmit), and intended use (resonant nuclei, frequency(ies), intended anatomical region)

(5) Imaging Protocols

A summary of the protocols and/or pulse sequences provided with the system.

(6) Patient Table

Dimensions and maximum supported patient weight

(7) Post processing features

A summary of the post-processing features available on the system, including the software version

(8) Accessories

A list of the accessories provided with the system (for example, physiological monitoring accessories such as EKG leads, pulse oximeters, respiratory and/or cardiac gating, elastography drivers)

C. User Manual

The User or Operator's Manual for a MRDD must address (1) the contraindications, warnings, precautions, and general risks associated with the device, and (2) contain a statement that "Caution: Federal law restricts this device to sale by or on the order of a physician" as required by 21 CFR Part 801. Moreover, the User or Operator's Manual for a MRDD and should contain the following information, as applicable:

(1) Indications for Use

The indications for use statement in the User Manual should be identical to the Indications for Use statement in FDA Form 3881 and the 510(k) Summary, if provided.

(2) Screening of patients for MRI

The User Manual should include recommended patient screening procedures and should clearly specify patients for whom exams are contraindicated and patients for whom special procedures must be followed. If applicable, FDA encourages you to refer to the standardized definitions of MR Safe, MR Conditional, and MR Unsafe defined in ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*.

(3) Magnetic field information.

The value and location of maximal |B|, |grad|B||, and |B|.|grad|B|| in patient-accessible areas should be provided.

(4) Emergency Procedures

Instructions for the end user should include emergency procedures for removing a patient rapidly from the MRDD.

(5) Excessive Noise

If noise within your MRDD can exceed 99 dBA, user instructions should state the specifications of the hearing protection required for patients. The User Manual should also specify the noise level at the control panel and whether hearing protection is required or recommended for operators.

(6) Controlled Access Area

Instructions should state that the user is responsible for establishing a controlled access area around the MRDD outside of which the magnetic field does not exceed 0.9 mT (9 gauss). FDA recommends use of 0.9 mT to establish the controlled access area, consistent with IEC 60601-2-33. As a more conservative limit, manufacturers may also continue to recommend 0.5 mT as the controlled access area in their labeling. Recommendations for the size and shape of this area based on the fringe field of the MRDD in all three dimensions should be specified, accompanied by a sketch.

The need for the controlled access area should be explained. You should provide recommendations for identification of the controlled access area (for example, markings, barriers or signs in accordance with the warning symbol depicted in ISO 7010 *Graphical symbols – Safety colours and safety signs – Registered safety signs*).

The User Manual should state the dangers of introducing equipment (such as patient monitoring, life support and emergency care equipment) not recommended for use in the controlled access area into the controlled access area. The User Instructions should also explain that even MR Conditional devices or equipment may be capable of causing injury if the specific conditions of safe use are not followed.

(7) Liquid Cryogens

For those MRDDs that use cryogens, the user instructions should include information about the potential hazards of cryogens, procedures to be followed after gas release, precautions against lack of oxygen, use of non-magnetic containers for cryogens, and procedures to be followed if flammable materials are found near cryogen containers.

Instructions should provide information on maintenance and inspection of the magnet and minimum cryogen levels, and specify the frequency at which cryogen levels should be checked by the user.

(8) Operating Modes

The operating modes of the system should be clearly explained.

(9) Emergency Shutdown

User Instructions should clearly explain the operation of the emergency field shutdown unit and when it is appropriate to use this feature.

(10) Emergency Responder Precautions

User Instructions should recommend that the end user discuss precautions with the local fire department and other emergency responders, and that site-specific emergency procedures be established.

(11) Quality Assurance

Instructions should describe the quality assurance procedures recommended for the user, including specifications of phantoms that should be used. The frequency of all recommended QA procedures should be specified.

(12) Maintenance

Instructions should include the recommended maintenance schedules for the equipment, including whether they should be performed by the user or company service personnel.

(13) Cleaning and Disinfection

Instructions for cleaning and disinfection should be included for components which come into contact with the patient or are intended for invasive use and are reusable (for example, endocavitary coils).

D. Site Planning Information

The site planning information should contain the following recommendations and information:

(1) Audio and Visual Contact with Patient

Design specifications for the scan room should include equipment to enable audio and visual contact with the patient during the examination.

(2) Magnetic Fringe Field

Magnetic field plots describing the 3D magnetic field created by the MRDD in a typical installation should be provided. Each plot should contain at least the iso-magnetic field contours with values of 0.5 mT, 0.9 mT, 3 mT, 5 mT, 10 mT, 20 mT, 40 mT and 200 mT, as well as a distance scale and a superimposed outline of the magnet.

(3) Liquid Cryogens and Cryogenic Gases

For superconducting magnets, the design of a venting system connected to an area outside the examination room that has been designed to withstand a quench should be provided.

(4) Decay Characteristics of the Magnetic Field

For superconducting and resistive magnets the decay characteristics of the magnetic field in the event of a quench or emergency field shut-down should be provided. These characteristics should indicate

the time from activation of the emergency field shut-down unit to the moment at which the field strength in the center of the magnet has fallen to 20 mT. Instructions should also be given regarding where and how to install the actuator of the emergency field shutdown unit.

(5) Additional Information

Information on the "Special Environment" specifications in IEC 60601-1-2 and how the special environment is implemented, including information on how integrity should be maintained during operation.