Magnetic Resonance (MR) Coil – Performance Criteria for Safety and Performance Based Pathway

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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

Preface

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Magnetic Resonance (MR) Coil – Performance Criteria for Safety and Performance Based Pathway

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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This draft guidance provides performance criteria for magnetic resonance (MR) coils in support of the Safety and Performance Based Pathway.[1] Under this framework, submitters planning to submit a 510(k) using the Safety and Performance Based Pathway for MR coils will have the option to use the performance criteria proposed in this draft guidance to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of a predicate device.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.[3]

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

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

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

be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Scope/Device Description

The MR coils that are the subject of this guidance are intended to produce images of human anatomy for general diagnostic use by trained clinicians. These MR coils are Class II and are regulated under 21 CFR 892.1000 Magnetic resonance diagnostic device, with the product code MOS (Coil, Magnetic Resonance, Specialty).

Intended Use/Indications for Use:
The MR coils that fall within the scope of this guidance document are intended for hydrogen/proton imaging. These devices are intended to have no patient contact or intended only for limited contact with intact skin (i.e., no endocavity coils). MR coils intended for 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) or specifically intended for use with imaging agents are out of the scope of this document.

Device Design Characteristics:
The MR coils that fall within the scope of this guidance document are designed to be air-cooled (i.e., no water-cooled or cryogen-cooled electronics). In addition, only receive-only RF coils are within the scope of this guidance.

General guidance that is beyond the scope of this safety and performance guidance document regarding submission of a 510(k) for MR coils (i.e., labeling), can be found in FDA's guidance Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices.[4]

Where FDA determines that additional data are necessary to make these determinations, the Agency may, on a case-by-case basis, review that data before determining whether or not the device is appropriate for the Safety and Performance Based Pathway. In situations, where you determine that additional testing outside of those identified in this guidance are necessary to make a determination regarding eligibility into the Safety and Performance Based Pathway, we would encourage sponsors to submit a Pre-Submission[5] to engage in discussion with FDA prior to submission of the 510(k).

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

III. Testing Performance Criteria

If your device is appropriate for submission through the Safety and Performance Based Pathway, and you choose to use that option, you do not need to provide direct comparison testing against a legally marketed predicate device to demonstrate substantially equivalent performance characteristics. To ensure that the performance criteria outlined in this guidance remain contemporary and take into account relevant data from recent clearances, FDA recommends that you provide a results summary for all tests evaluated in addition to the other submission information (e.g., Declaration of Conformity (DoC)) identified for each test or evaluation below. Unless otherwise identified in the submission information sections below, test information such as results summary, test protocols, or complete test reports should be submitted as part of the 510(k) as described in FDA's guidance Safety and Performance Based Pathway.[6] For additional information regarding the submission of non-clinical bench testing information, please see FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.[7]

1. **Test name:** Image Signal to Noise (SNR)
   Methodology: Conformance to one of the following FDA recognized consensus standards (as applicable):
   - National Electrical Manufacturers Association (NEMA) MS 1 *Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging*
   - NEMA MS 6 *Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI)*
   - NEMA MS 9 *Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)*

   Performance Criteria: >140 (using the lowest SNR measure over all imaging coils, planes, and anatomical regions)
   Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions for MR coils previously found to be substantially equivalent.
   Submission Information: Results summary and Declaration of Conformity (DoC)

2. **Test name:** Image Uniformity
   Methodology: Conformance to one of the following FDA recognized consensus standards (as applicable):
   - NEMA MS 3 *Determination of Image Uniformity in Diagnostic Magnetic Resonance Images*
   - NEMA MS 6 *Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI)*

[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway
[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

- NEMA MS 9 *Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)*

Performance Criteria: Worst-case non-uniformity < 50%
Performance Criteria Source: Criteria are based on aggregated data submitted to FDA in 510(k) submissions for MR coils previously found to be substantially equivalent.
Additional Considerations: The gray-scale uniformity map methods described in NEMA MS 3 section 2.3.3 Gray-Scale Uniformity Map, NEMA MS 6 section 2.6 Primary Measurement Procedure for Image Uniformity, and NEMA MS 9 (which refer to the previously mentioned sections of NEMA MS 3 and NEMA MS 6) are excluded because these methods do not provide results that lend to simple objective assessment and performance criteria.
Submission Information: Results summary and DoC

3. **Test name:** Surface heating
Methodology: No standardized test method currently available
Performance Criteria: <41°C for all potentially patient contacting parts under both normal use and single fault (coil not plugged in) conditions
Performance Criteria Source: FDA currently recognized version of ANSI/AAMI ES60601-1 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, Section 11.1.2 Temperature of Applied Parts
Submission Information: Complete test report

4. **Test name:** Acquired Image Quality
Methodology: Sample clinical images from all target anatomical locations reviewed to determine images produced by the device are of sufficient quality for diagnostic use.
Performance Criteria: Statement from a US Board Certified radiologist that images are of diagnostic quality and sample clinical images to support the ability of your system to generate diagnostic quality images.
Performance Criteria Source: FDA guidance document Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices[8]
Additional Considerations: Due to the subjective nature of this assessment, you should provide a small, representative subset of clinical images.
Submission Information: Statement from US Board Certified radiologist including a description of the sequences and anatomical regions reviewed by the radiologist and small, representative subset of clinical images including description of the target anatomical site, scan parameters employed, and the total imaging time for each image.

5. **Test name:** Decoupling circuit
Methodology: Inspection of circuit diagrams
Performance Criteria: Presence of decoupling mechanisms
Performance Criteria Source: FDA guidance document Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices

Submission Information: Circuit diagrams and description of decoupling mechanism

6. **Test name:** EMC – Immunity, electrostatic discharge
Methodology: FDA currently recognized version of 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*
Performance Criteria: pass at ±8 kV contact, ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Performance Criteria Source: Current version of FDA recognized consensus standard IEC 61000-4-2: *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques*
Additional Considerations: Due to options within the standard, DoC should identify options chosen
Submission Information: Results summary and DoC

7. **Test name:** General electrical/mechanical safety
Methodology: Current version of FDA consensus standards AAMI/ANSI ES60601-1 *Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance* and 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*
Performance Criteria: Demonstration that the device performs safely and as anticipated in its intended use environment
Performance Criteria Source: FDA currently recognized version of AAMI/ANSI ES60601-1: *Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance* and 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*
Additional Considerations: Due to options within the standard, DoC should identify options chosen
Submission Information: Results summary and DoC

Biocompatibility Evaluation:

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation you should use Attachment A of CDRH's guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,[9] referred to in the rest of this document as the CDRH Biocompatibility Guidance for brevity. FDA considers the devices covered by this guidance to be categorized as Surface Devices with intact skin and contact duration of ≤ 24 hours, and you should assess the endpoints below per Attachment A of the CDRH Biocompatibility Guidance.

- Cytotoxicity
- Sensitization

[9] 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

- Irritation or Intracutaneous Reactivity

Rationale in Lieu of Testing: If the subject device is manufactured from the identical raw materials using identical manufacturing processes as a predicate device with the same type and duration of tissue contact, and any changes in geometry are not expected to impact the biological response, this is typically sufficient to establish substantially equivalent biocompatibility, if documentation such as that outlined in Attachment F of the CDRH Biocompatibility Guidance is also provided.

Testing: If you determined that testing is needed to address some or all of the identified biocompatibility endpoints, FDA recommends that complete test reports be provided for all tests performed unless a declaration of conformity without supplemental information can be appropriately provided, per Attachment E of the CDRH Biocompatibility Guidance. Any test-specific positive, negative, and/or reagent controls should perform as expected, and protocol deviations should be thoroughly described and justified; however, note that certain protocol deviations may invalidate comparison to the performance criteria listed below and require submission of a Traditional, Special, or Abbreviated 510(k).

8. **Test name:** Biocompatibility endpoints (identified from CDRH Biocompatibility Guidance)
   Methodology: FDA currently-recognized versions of biocompatibility consensus standards
   Performance Criteria: All direct or indirect tissue contacting components of the device and device-specific instruments should be determined to have an acceptable biological response.
   Performance Criteria Source: The CDRH Biocompatibility Guidance
   Additional Considerations: For any biocompatibility test samples with an adverse biological response, the biocompatibility evaluation should explain why the level of toxicity seen is acceptable. Some comparison testing against a legally marketed predicate may be necessary (and is considered acceptable under the Safety and Performance Based Pathway) to support such a rationale as explained in the CDRH Biocompatibility Guidance. For standard biocompatibility test methods that include comparison device control samples, the legally marketed comparison device control samples should perform as expected, as specified above for the subject device samples.
   Submission Information: Refer to CDRH Biocompatibility Guidance