

**STANDARDIZED 510(k) PRE-MARKET NOTIFICATION  
SUBMISSION TEMPLATE FOR RF COIL ACCESSORIES  
INTENDED FOR USE WITH MAGNETIC RESONANCE  
DIAGNOSTIC IMAGING DEVICES**

**NEMA**

Prepared by the  
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Fonar Corporation  
GE Medical Systems, Inc.  
Greatbatch Scientific  
Hitachi Medical Systems America, Inc.  
Medical Advances Inc.  
Philips Medical Systems  
Picker International, Inc.  
Siemens Medical Systems, Inc.  
Toshiba America MRI, Inc.

## STATEMENT OF APPLICABILITY

The MR Section of the National Electrical Manufacturers Association (NEMA), in response to a request from the Food and Drug Administration's Center for Devices and Radiological Health Office of Device Evaluation (FDA/CDRH/ODE), has developed this guidance document. This document is intended for use by the FDA, 3<sup>rd</sup>-Party reviewers of 510(k) Pre-market notifications, and by manufacturers themselves. Full or partial usage of this guidance document is optional, voluntary, and purely at the discretion of these intended audiences.

This guidance document provides suggested contents of 510(k) premarket notification submissions for RF coil accessories intended for use with magnetic resonance diagnostic imaging devices. The scope of this document is limited to 'technical claims,' which do not change the FDA-approved intended use(s) for MRI. New 'diagnostic or clinical claims' may require additional information beyond the scope of this document.

This guidance document provides suggested formatting and layout of the 510(k) premarket notification submission.

## Standardized MR Template for RF Coil Submissions

### General format:

- 1.0 Cover Letter
- 2.0 Table of Contents
- 3.0 Attachment 1: (optional) FDA CDRH/ODE Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices [DRAERD] Checklist with Page References
  - ▼ Note: Attachment 1, FDA/CDRH/ODE's Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices [DRAERD] Checklist with Page References, is optional if Item 2.0, Table of Contents, is in sufficient detail, and contains the same information as the DRAERD Checklist.
- 4.0 Attachment 2: 510(k) Summary of Safety and Effectiveness (or Statement)
- 5.0 Attachment 3: Statement of Indication for Use (FDA Form)
- 6.0 Attachment 4: Software Documentation and Summary Certification
  - ▼ Note: Attachment 4, Software Documentation and Summary Certification, is not applicable, if software was not changed in order to support full functionality of the RF Coil.
- 7.0 Attachment 5: Device Characteristics, Figure/Illustration/Photo(s), Imaging Performance Parameters
- 8.0 Attachment 6: Safety
- 9.0 Attachment 7: Labeling
- 10.0 Attachment 8: Comparison to Predicate Device
- 11.0 Attachment 9: Testing Procedures and Results (incl. Clinical Images)

### Detailed format:

- 1.0 Cover Letter
  - 1.1 Statement: 510(k) submission prepared according to the requirements of 21CFR §807.87. The 510(k) Summary of Safety and Effectiveness (or Statement) may be found in Attachment 2.
  - 1.2 DEVICE NAME:                   Magnetic Resonance Diagnostic Device
    - Classification Panel:           Radiology
    - Classification Number:       892.1000 Magnetic Resonance Diagnostic Device
    - Product Nomenclature:       System, Nuclear Magnetic Resonance Imaging System, Nuclear Magnetic Resonance Spectroscopic Coil, Magnetic Resonance Specialty
    - Product Code:                   90LNH (imaging)
    - 90LNI (spectroscopy)
    - 90MOS (magnetic resonance specialty coil)
    - Trade/Proprietary Name:      to be provided by submitting company.

1.3 ESTABLISHMENT REGISTRATION NUMBER: to be provided by submitting company.

1.4 DEVICE CLASS:

FDA has classified Magnetic Resonance Imaging Devices as Class II.

1.5 APPLICABLE PERFORMANCE STANDARDS:

No applicable performance standards have been issued under section 514 of the Food, Drug, and Cosmetic Act.

Applicable Voluntary Safety Standards:

V Note: The manufacturer responsible for the 510(k) submission may pick and choose from the following standards as appropriate.

I IEC-60601-1, International Electrotechnical Commission, Medical Electrical Equipment, Part 1: General Requirements for Safety

I UL 2601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety

I IEC-60601-2-33, International Electrotechnical Commission, Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis.

I UL 94 Tests for Flammability of Plastic Materials for Parts in Devices and Appliances

I Any other applicable standards

Applicable Voluntary Measurement Standards:

V Note: The manufacturer responsible for the 510(k) submission may pick and choose from the following standards as appropriate.

I NEMA MS-1 Determination of Signal-to-Noise (SNR) in Diagnostic Magnetic Resonance Images

I NEMA MS-3 Determination of Image Uniformity Diagnostic Magnetic Resonance Images

I NEMA MS-6 Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images

I NEMA MS-8 Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems

1.6 PROPOSED LABELS, LABELING, AND ADVERTISEMENTS:

1.6.1 Device Characteristics:

Briefly describe major device characteristics, and provide a reference to detailed documentation in Attachment 5...

I Introduction (physical description of features, positioning information, list of / identification of applicable MRI systems, summary specifications)

I Reason for submission (new, modified, safety/complaint/MDR)

I Statement: Software (was/was not) revised in order to support the RF coil, and, if appropriate, provide a reference to Summary Software Documentation and Certification in Attachment 4

### 1.6.2 Safety Parameters:

Briefly describe device safety characteristics, and provide a reference to detailed documentation in Attachment 6; may possibly include...

- I Static Magnetic Field (at which coil is designed to be used)
- I Decoupling circuitry (provide schematics, description of operation)
- I SAR (Transmit/Receive coils)
- I Power Input protection (Transmit/Receive Coils)
- I Cleaning/Disinfection/Sterilization (statement of method/approach), as appropriate, and provide a reference to Attachment 6 for additional information
- I Biocompatibility (data or certification, materials that contact the patient) — required for materials not in 'routine use' in MRI, or for invasive uses (e.g., endocavity)

### 1.6.3 Imaging Performance Parameters

Briefly describe device imaging performance characteristics, and provide a reference to detailed documentation in Attachment 5...

- I SNR (per NEMA or other method)
- I Image Uniformity (per NEMA or other method)

For Phased Array coils, provide SNR and Image Uniformity for the entire array, and/or for relevant coil combinations.

### 1.6.4 Intended Uses

- I Generic MR Intended Use

(Note:

*Intended Use* refers to the general functional use of the device, i.e., the principal effect of the radiation/tissue interaction which represents a broad or general indication for use of the device.

*Indication for Use* refers to the specific surgical, therapeutic, or diagnostic use, or group of similar uses, of the device, i.e., the disease, condition, or pathology for which the principal effect of the device is used to prevent, treat, cure, mitigate, or diagnose.)

Provide a reference to FDA Form 'Indications for Use' in Attachment 3.

### 1.6.5 Proposed Labeling:

Summarize description of new labeling and/or changes to existing labeling; Provide a reference to documentation in Attachment 7...

### 1.6.6 Kits:

Not applicable to MRI at this time.

1.7 TESTING PROCEDURES AND RESULTS:

Summarize description of testing procedures, results, and clinical images. Provide a reference to documentation and clinical images provided in Attachment 9.

1.8 EQUIVALENCY INFORMATION:

Provide a reference to Predicate Device documentation provided in Attachment 8.

- I Identification of predicate device(s)
- I Predicate Device 510(k) number(s) - if available
- I Comparison tables

1.9 DRAWINGS:

Provide a reference to the following illustrative documentation provided in Attachment 5...

- I Dimensioned figure, illustration, and/or photo(s)

1.10 ADDRESS OF MANUFACTURING FACILITIES:

To be provided by submitting company.

1.11 ADDRESS OF STERILIZATION FACILITIES:

If applicable, to be provided by submitting company.

1.12 CERTIFICATION STATEMENT

We believe this narrative, the foregoing information, and the referenced attachments demonstrate the substantial equivalence of the device name to the predicate device(s), and will be sufficient for the Food and Drug Administration to reach a decision on this submission.

1.13 TRUTHFUL AND ACCURATE CERTIFICATION STATEMENT

I certify that, in my capacity as [the position held in company] of [company name], I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

1.14 CONTACT INFORMATION

1.14.1 Telephone number

1.14.2 Telefax number

1.14.3 E-mail address

1.14.4 Official Correspondent name, signature

2.0 Table of Contents / List of Attachments

3.0 **Attachment 1:** (optional) FDA CDRH/ODE Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices [DRAERD] Checklist with Page References

- ✓ Note: Attachment 1, FDA/CDRH/ODE's Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices [DRAERD] Checklist with Page References, is optional if Item 2.0, Table of Contents, is in sufficient detail, and contains the same information as the DRAERD Checklist.

4.0 **Attachment 2:** 510(k) Summary of Safety and Effectiveness (if not Statement)

Refer to Federal Register notice defining contents of 510(k) Summary of Safety and Effectiveness (FR Doc. 94-30422, Docket No. 91N-0388, Vol 59, No.239, dated December 14, 1994, ppg 64287-64296).

Either provide:

- a. A summary of the safety and effectiveness information upon which an equivalence determination could be based; or...
- b. A statement that safety and effectiveness information will be made available to interested persons upon request (Safety and Effectiveness information refers to information in the pre-market notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicated device(s), or performance or clinical testing information).

If a 510(k) Summary of Safety and Effectiveness is provided, include the following...

- 4.1 Case for Substantial Equivalence
- 4.2 Comparison to Predicate Device ('public comparison')

5.0 **Attachment 3:** Statement of Indication for Use (FDA form)

Refer to item 1.6.4 above for differentiation between Intended Use and Indication for Use.

6.0 **Attachment 4:** Summary Software Documentation and Certification

- ✓ Note: Attachment 4, Software Documentation and Summary Certification, is not applicable, if software was not changed in order to support full functionality of the RF Coil.

If software was changed, identify minimum system software version for which RF coil is intended.

This section describes the *general* software development process, usually becomes somewhat standard and boilerplate, and can often be 'recycled' in whole or in part from 510(k) submission to submission.

This section is developed by the manufacturer in response to 1991 'Reviewer Guidance for Computer-controlled Medical Devices.' The content of this section may require updating in order to comply with the final version of the draft 1996 'ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software.'

- V Note: Suggested paperwork reduction – include complete software documentation as part of ‘system’ or ‘major’ software submissions, then reference and include only items which have changed as part of subsequent submissions (changed items: hazard analysis, testing summary results, certification, etc.) Refer reviewer to system software documents.

Describe the five phases of software development:

- I Specifications/requirements
- I Design
- I Implementation
- I Verification and Validation
- I Maintenance

FDA-expected software documentation consists of the following items, with connectivity, continuity, and the traceability of concepts...

- 6.1 Level of Concern
- 6.2 System and Software Requirements and Design Document <sup>V</sup>
- 6.3 Hazard Analysis Document <sup>V</sup>
- 6.4 Software Development Manual/Software Development Plan <sup>V</sup>
- 6.5 Software Testing, Verification and Validation Document
- 6.6 Software Certification

- V Note: Suggested paperwork reduction – include these software documents only as part of ‘system’ or ‘major’ software submissions. Documents ‘on-file’ for review as part of manufacturer’s cGMP/Quality Systems files.

7.0 **Attachment 5:** Device Characteristics, Figure/Illustration/Photo(s), Imaging Performance Parameters

7.1 Description of Device Characteristics (as needed)

- I Introduction (physical description of features, positioning information, list of / identification of applicable systems)
- I Reason for submission (new, modified, safety/complaint/MDR)
- I Statement: Software (was/was not) revised in order to support the RF coil, and, if appropriate, provide a reference to Summary Software Documentation and Certification in Attachment 4
- I Indications for use (generic MR Indications for Use)
- I Operating principles, technical descriptions (include decoupling diagram), description of how it works (with technical references, if applicable/needed)
- I Specifications (Anatomical coverage, ROI, SNR, Uniformity, biocompatibility)
- I Literature references

7.2 Dimensioned figure, illustration, and/or photo(s)

## 7.3 SNR (per NEMA standard or other method)

Provide phantom descriptions, test methods, and results. For coils requiring multiple receiver channels (e.g., Phased Array), provide SNR for relevant coil combinations.

**V** Note: For nuclei other than proton, performance parameters should be defined as appropriate.

## 7.4 Image Uniformity (per NEMA standard or other method)

Provide phantom descriptions, test methods, and results. For coils requiring multiple receiver channels (e.g., Phased Array), provide Image Uniformity for relevant coil combinations.

**V** Note: For nuclei other than proton, performance parameters should be defined as appropriate.

8.0 **Attachment 6: Safety**

Provide data, as needed:

## 8.1 Static Magnetic Field (at which coil is designed to be used)

## 8.2 Decoupling circuitry (provide schematics, description of operation, block diagrams to describe circuit)

## 8.3 Worst-case SAR calculations - Transmit/Receive coils (per NEMA standard)

## 8.4 Power Input protection (Transmit/Receive coils)

8.5 Cleaning/Disinfection/Sterilization For **sterilization**: provide a statement of method/approach, test data, Sterilization Assurance Level [SAL]

## 8.6 Biocompatibility: provide data or certification statement, list of materials that contact the patient, diagram/figure identifying material(s) and location(s) — required for materials not in 'routine use' in MRI, or for invasive uses (e.g., endocavity)

9.0 **Attachment 7: Labeling**

Provide, as needed:

## 9.1 Specifications

## 9.2 Marketing Claims

## 9.3 Brochures and Advertising

## 9.4 Operator's Manual / excerpts

## 9.4.1 Instructions for Proper Use - see §9.6 below

## 9.4.2 Patient Positioning instructions

9.4.3 Quality Assurance procedure (contained in System *and/or* RF Coil Operator's Manual), including, if needed, description of any special phantom supplied with RF coil, and recommended step(s) for resolution of the problem

## 9.4.4 Preventive Maintenance procedure, if needed (usually contained within System Operator's Manual)

9.4.5 Prescription Device Label/Statement.

- V Note: System and/or RF Coil Operator's Manual should contain the Prescription Device Label/Statement. If the System Operator's Manual contains the statement, then include a copy of the statement within the 510(k) submission.

9.5 Cleaning Instructions (for cleaning/disinfecting/sterilization)

9.6 Instructions for Use (usually includes, but not limited to, appropriate material from NEMA MR Section 'Accessory Equipment Considerations with Respect to Magnetic Resonance Imaging Compatibility' or similar, and Warnings statements listed below)

- V Note: It may be helpful to the clinical users to provide a rationale for these Warnings statements.

- V Note: System and/or RF Coil Operator's Manual should contain these, or similar, Warnings Statements. If the System Operator's Manual contains these statements, then include a copy of the statements within the 510(k) submission.

- (a.) Connect the surface coil cable only to the connector as prescribed in this manual.
- (b.) Do not use coils, cables, or gating leads with exposed metal surfaces or abraded insulation.
- (c.) Remove unused or not properly connected coils, cables, and gating leads from the magnet bore before performing a scan.
- (d.) Position the patient and the surface coil and cable or gating sensor and lead(s) as prescribed in this manual.
- (e.) Check the surface coil cable or gating lead(s) after positioning the patient to ensure that the cable or lead(s) does not form a loop within the magnet bore; minimize the length of cable or lead(s) within the magnet bore.
- (f.) Check that the surface coil cable or gating lead(s) does not directly contact any part of the patient. (It is recommended that padding or other materials be used to separate the cable or lead(s) from the patient.)
- (g.) Check that the cable or lead(s) does not touch the sides of the magnet bore.
- (h.) Immediately stop the MR scan acquisition if the patient notes or complains of a tingling and/or heating sensation.
- (i.) By law, clinical users are required to report adverse events (deaths, serious illnesses and injuries) associated with the use of medical devices. These adverse events, or Medical Device Reports (MDRs), should be reported to the FDA and to the manufacturer, using the MedWatch reporting program. MDR information may be obtained from the FDA via telephone at 301-594-2735, or via internet at <http://www.fda.gov/medwatch>.

- V Note: Depending upon the RF Coil's Indications for Use, a statement regarding Latex Sensitivity may be required.

10.0 **Attachment 8:** Comparison to Predicate Device

'Private' or 'non-public' comparison

10.1 Narrative (optional) - provide an overview summary of the comparison to the Predicate Device.

10.2 Tabular Comparison - provide a comparison of **major** similarities and differences (as opposed to unimportant details) between the subject device and the predicate device.

10.2.1 Characteristics

- I Intended Use
- I Applicable systems
- I Mode of Operation
- I Coil Configuration (linear, quad, array, etc.)

10.2.2 Performance

- I SNR
- I Uniformity

10.2.3 Safety

- I SAR (T/R Coils)
- I Power input protection (T/R Coils)
- I Decoupling circuitry
- I Materials

10.2.4 Technological

10.2.5 Predicate Device Information and Promotional Literature

10.2.6 Labeling / Advertising / Specifications / Freedom of Information Act [FOIA] Information

11.0 **Attachment 9:** Laboratory/Bench Data

Specific, detailed *Performance Evaluation, Clinical Images, Evaluation Methods, and Results* relevant to the device.

11.1 Laboratory Testing

11.1.1 Performance Evaluation

- I SNR
- I Uniformity
- I Phantom images (optional)

▼ Note: For nuclei other than proton, performance parameters should be defined as appropriate.

### 11.1.2 Safety Evaluation

- I Transmit/Receive only: Worst-case SAR, test methods, and results

### 11.1.3 Software Evaluation

- V Note: This section is optional, if software was not revised in order to support RF coil functionality.
- I Summary of verification and validation testing to ensure that system requirements are met (if N/A, state reason why)

### 11.2 Clinical Images

- I Clinical Images with Supporting Documentation

## 12.0 References

The following references were used in the development of this document. As FDA guidance documents are rapidly evolving, these documents may become outdated. The reader is advised to take appropriate measures to ensure use of current documents and the practices described therein.

- 12.1 DHHS/FDA/CDRH/ODE. 1987. Tripartite Biocompatibility Guidance for Medical Devices. September 1986. \*obsolete\*
- 12.2 FDA/CDRH/ODE/DRAERD. 1988. Guidance for Content and Review of a Magnetic Resonance Diagnostic Device 510(k) Application. August 2, 1988.
- 12.3 FDA/CDRH/ODE. 1991. Reviewer Guidance for Computer-Controlled Medical Devices Undergoing 510(k) Review. August 29, 1991.
- 12.4 DHHS/FDA/CDRH/ODE. 1995. #G95-1 Use of International Standard ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. May 1, 1995.
- 12.5 FDA/CDRH/ODE/DRAERD. 1996. Dr. Lillian Yin. Letter to NEMA Magnetic Resonance Section Technical Committee Regarding Biocompatibility. February 15, 1996.
- 12.6 FDA/CDRH Software Task Force Group. 1996. ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software. September 3, 1996. \*draft\*
- 12.7 NEMA MR Section. 1997. Accessory Equipment Considerations with Respect to Magnetic Resonance Imaging Compatibility. April 1997.
- 12.8 FDA/CDRH/ODE. 1997. General Principles of Software Validation. June 9, 1997. \*draft\*
- 12.9 FDA/CDRH/ODE/DRAERD. 1997. Dr. Lillian Yin. Letter to NEMA Magnetic Resonance Section Regarding Software Level of Concern. September 2, 1997.
- 12.10 FDA/CDRH/CIDB/DRAERD. 1997. Guidance for Magnetic Resonance Diagnostic Devices - Criteria for Significant Risk Investigations. September 29, 1997.
- 12.11 NEMA. MS-1 Determination of Signal-to-Noise (SNR) in Diagnostic Magnetic Resonance Images. 1994.
- 12.12 NEMA. MS-3 Determination of Image Uniformity Diagnostic Magnetic Resonance Images. 1989 (1994).
- 12.13 NEMA. MS-6 Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images. 1991.
- 12.14 NEMA. MS-8 Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems. 1993.

These documents are in part available from the FDA via Internet (<http://www.FDA.gov>), from the Division of Small Manufacturer's Assistance (800-638-2041; 301-443-6597), from the FDA via Fax-on-Demand (800-899-0381; 301-827-0111), Global/IHS (US: 800-854-7179, Int'l: 303-397-7956; Internet: <http://global.ihs.com>) and the American National Standards Institute (212-642-4900).