

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

NEMA

**Prepared by the
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MR SECTION MEMBER COMPANIES:

Bruker Instruments, Inc.
Caprius
Elsint, Inc.
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, 3rd-Party reviewers of 510(k) Pre-market notifications, and by manufacturers themselves. Usage of this guidance document is voluntary.

This guidance document provides suggested contents of 510(k) premarket notification submissions for software intended for use with magnetic resonance diagnostic imaging devices. 'Software' may range in subject from code to calculate image-derived data, perform image manipulation ('filtering'), acquire images ('pulse sequences'), or operate an entire MR system ('operating systems'). 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 Software 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
- 7.0 Attachment 5: Device Software Characteristics
- 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 System, Image Processing
Product Code:	90LNH (imaging) 90LNI (spectroscopy) 90LLZ (image processing system)
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:

- ❖ Note: The manufacturer responsible for the 510(k) submission may pick and choose from the following standards as appropriate.
- IEC-60601-2-33, International Electrotechnical Commission, Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis.
- UL1998, Safety-Related Software - software whose failure could result in a risk of injury to persons or loss of property
- IEC-60601-1-4, International Electrotechnical Commission, Medical Electrical Equipment, Part 1: General Requirements for Safety, Collateral Standard: Safety Requirements for Programmable Electronic Medical Systems
- Any other applicable standards

Applicable Voluntary Measurement Standards:

- ❖ Note: The manufacturer responsible for the 510(k) submission may pick and choose from the following standards as appropriate.
- NEMA MS-4 Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices
- NEMA MS-7 Measurement Procedure for Time-Varying Gradient Fields (dB/dt) for Magnetic Resonance Imaging Systems
- 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...

- Introduction (physical description of features, list of / identification of applicable systems, summary specifications)
- Reason for submission (new, modified, safety/complaint/MDR)

1.6.2 Safety Parameters:

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

- Static Magnetic Field
- SAR
- dB/dt
- Acoustic Noise

1.6.3 Intended Uses

- 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.

1.6.4 Proposed Labeling:

Briefly describe new labeling and/or changes to existing labeling; Provide a reference to documentation in Attachment 7...

1.7 TESTING PROCEDURES AND RESULTS:

Briefly describe 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.

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

1.9 DRAWINGS:

Not applicable.

1.10 ADDRESS OF MANUFACTURING FACILITIES:

To be provided by submitting company.

1.11 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.

1.12 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.

1.13 CONTACT INFORMATION

1.13.1 Telephone number

1.13.2 Telefax number

1.13.3 E-mail address

1.13.4 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 §1.6.3 above for differentiation between Intended Use and Indication for Use.

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

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.'

- ❖ 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:

- Specifications/requirements
- Design
- Implementation
- Verification and Validation
- 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 ❖

6.3 Hazard/Risk Analysis Document ❖

6.4 Software Development Manual/Software Development Plan ❖

6.5 Software Testing, Verification and Validation Document

6.6 Software Certification

- ❖ 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 : New or Modified Software

- ❖ Note: this section is applicable to proton, other nuclei, metabolites and/or spectroscopic data.
- ❖ Note: as appropriate, reference(s) may be made to previously published data in literature; provide references and literature summary to most pertinent articles.

7.1 Identify and describe performance capabilities of software (specifications)

7.2 Scan Control : Acquisition Software

- Pre-scan and scan setup procedures
- Pulse sequence diagrams (RF and Gradient)
- Technical descriptions of operation (Phase descriptions, etc.)
- Algorithms for SAR, dB/dt calculations
- Artifacts: describe potential artifacts, identification, ways to minimize

7.3 Reconstruction : Operations performed upon raw data

- Technical: reconstruction algorithms, raw data handling and manipulation
- Artifacts: describe potential artifacts, identification, ways to minimize

7.4 Post-processing : Images and/or Image-Derived Data

Assumes that image processing operations are performed upon existing images, not raw data.

- Technical descriptions of algorithm, operation, tradeoffs, limitations, accuracy of calculations and range of operating conditions
- Artifacts: describe potential artifacts, identification, ways to minimize

8.0 **Attachment 6:** Safety

- ❖ Note: Assumes operating conditions below Second Level Controlled Operating Mode, as defined in IEC Collateral Standard 60601-2-33, or below levels identified in FDA/CDRH/CIDB/DRAERD's Guidance for Magnetic Resonance Diagnostic Devices - Criteria for Significant Risk Investigations, dated September 29, 1997.

Provide data as needed:

8.1 Static Magnetic Field

8.2 Worst-case SAR calculations (per NEMA standard)

8.3 dB/dt calculations (per NEMA standard)

- ❖ Note: dB/dt may be measured to NEMA standard MS-7, and according to FDA's Draft MRI Guidance Update for dB/dt, dated April 21, 1995.

8.4 Acoustic Noise data measurements (per NEMA standard)

9.0 **Attachment 7:** Labeling (for the software device)

Provide, as needed:

9.1 Specifications

9.2 Marketing Claims

9.3 Brochures and Advertising ❖

9.4 Operator's Manual ❖

9.5 Operator's Manual excerpts ❖

9.6 Prescription Device Label/Statement

- ❖ Note: System and/or Software 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.

- ❖ Note: Draft version acceptable.

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 Performance

10.2.2 Safety

10.2.3 Technological

10.2.4 Predicate Device Information and Promotional Literature

10.2.5 Labeling / Advertising / Specifications / Freedom of Information Act (FOIA) Information

10.2.6 Intended Use

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

11.1.2 Test Procedures

11.1.3 Analysis of Results

11.2 Clinical Images with Supporting Documentation

11.3 Reference(s) - (optional) - provide citations to previously published data in literature; provide references and literature summary to most pertinent articles.

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 FDA/CDRH/CIDB/DRAERD. 1995. Draft MRI Guidance Update for dB/dt. April 21, 1995.
- 12.5 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.
- 12.6 FDA/CDRH/ODE/DRAERD. 1996. Dr. Lillian Yin. Letter to NEMA Magnetic Resonance Section Technical Committee Regarding Biocompatibility. February 15, 1996.
- 12.7 FDA/CDRH Software Task Force Group. 1996. ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software. September 3, 1996. *draft*
- 12.8 NEMA MR Section. 1997. Accessory Equipment Considerations with Respect to Magnetic Resonance Imaging Compatibility. April 1997.
- 12.9 FDA/CDRH/ODE. 1997. General Principles of Software Validation. June 9, 1997. *draft*
- 12.10 FDA/CDRH/ODE. 1997. Guidance of Off-the-Shelf Software Use in Medical Devices. June 4, 1997. *draft*
- 12.11 FDA/CDRH/ODE/DRAERD. 1997. Dr. Lillian Yin. Letter to NEMA Magnetic Resonance Section Regarding Software Level of Concern. September 2, 1997.
- 12.12 FDA/CDRH/CIDB/DRAERD. 1997. Guidance for Magnetic Resonance Diagnostic Devices - Criteria for Significant Risk Investigations. September 29, 1997.
- 12.13 NEMA MS-4 Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices. 1997.
- 12.14 NEMA MS-7 Measurement Procedure for Time-Varying Gradient Fields (dB/dt) for Magnetic Resonance Imaging Systems. 1997.
- 12.15 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).