Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices

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Guidance for Industry and Food and Drug Administration Staff

Document issued on July 11, 2016.

The draft of this document was issued on November 2, 2015.

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Food and Drug Administration
Center for Devices and Radiological Health
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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov . Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2015-D-3787. Comments may not be acted upon by the Agency until the document is next revised or updated.

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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 and Scope

The Food and Drug Administration (FDA) has developed this document to describe relevant information that should be provided in a premarket submission, (i.e., premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, premarket notification [510(k)] submissions, investigational device exemption (IDE) applications and de novo requests), to support a claim of electromagnetic compatibility (EMC) for an electrically-powered medical device. Electrically-powered devices include those that are AC (mains) powered devices, battery powered devices, and active implantable devices. For the purpose of this document, EMC is defined as the ability of a device to function safely and effectively in its intended electromagnetic environment, including immunity to electromagnetic disturbance (interference[1]), without introducing excessive electromagnetic disturbances (emissions) that might interfere with other devices.

Typically, the review of EMC information in a submission is based on the risk associated with EMC malfunction or degradation of the device under review, as well as the use of appropriate FDA-recognized standards or appropriate consensus standards.

[1] According to International definitions, "disturbance" is the cause and "interference" is the effect. In the US, "interference" is often used interchangeably for both cause and effect though more often for the cause.

Manufacturers of electrically-powered medical devices often reference FDA-recognized consensus national or international standards for EMC in pre-market submissions. For medical electrical equipment or medical electrical systems (as defined in the International Electrotechnical Commission (IEC) 60601-1 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety and Essential Performance), manufacturers primarily reference the IEC 60601-1-2 standard or the equivalent United States (US) version.[2] In addition, there are device-specific consensus standards, or "particular" standards, under the IEC 60601-1 family (e.g., IEC 60601-2-X, where X denotes a particular device standard). These particular standards may augment or supersede the specifications in the IEC 60601-1-2 standard. There are also consensus standards for active implantable medical devices that include information on EMC. Some examples include International Organization for Standardization (ISO) 14708 Implants for surgery – Active implantable medical devices – Part 3: Implantable neurostimulators for Implantable neurostimulators and ISO 14117 Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices.

The items listed below are intended to help ensure that clear and consistent information are provided in premarket submissions regarding medical device EMC, and are consistent with the specifications included in the appropriate standards. For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database. The information in this guidance is intended to be used in conjunction with other FDA guidance documents, including device-specific guidances such as *Infusion Pumps Total Product Life Cycle*, and cross-cutting guidances such as *Design Considerations for Devices Intended for Home Use*.

FDA's guidance documents, including this guidance, 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 guidance means that something is suggested or recommended, but not required.

II. EMC Information

To facilitate premarket submissions and reviews, a claim of EMC for a device should be accompanied by the information listed below:

[2] IEC 60601-1-2 Edition 3: 2007: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, IEC 60601-1-2 Edition 4.0:2014: Medical Electrical Equipment, Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests, AAMI/ANSI/IEC 60601-1-2: 2007/(R)2012: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, and AAMI/ANSI/IEC 60601-1-2: 2014: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

A. The environments defined by the manufacturer for which the medical device is intended to be used;

B. a summary of the testing that was performed to support EMC;

C. the specifications of the standard that were met (including immunity test levels);

D. a summary of the device-specific pass/fail criteria used, including how the pass/fail criteria were derived. Each medical device should have specific criteria based on the device functions, indications, intended use, and essential performance. Particular device standards (e.g., IEC 60601-2-X, ISO 14708-3) may contain device-specific test methods and pass/fail criteria that can also be referenced;

E. the specific functions of the device that were tested (e.g., for IEC 60601-1-2, this should include performance that was determined by the manufacturer to be essential performance) and how these functions were monitored during testing. For example, use quantitative measurements and visual observation to monitor the specific functions of the medical devices. The monitoring system should not perturb the test;

F. specific information about the performance of the device during each test, demonstrating that the device met the emissions and immunity pass/fail criteria. This includes a summary of any device effects, disruptions, or degradations observed during testing and how these were mitigated (see point J below);

G. an identification of and a justification for any of the standard's allowances that were used, if applicable;

H. a description of and justification for any deviations from the specifications of the referenced standard. The justification should explain how the deviations would not compromise the safety and effectiveness (performance) of the device;

I. the device labeling and evidence of compliance with the reference standard's labeling (identification, marking and documents) specifications; and

J. a detailed description of all changes or modifications that were made to the tested version of the device in order to pass any of the EMC tests. If modifications were made, a statement should be included in the premarket submission indicating that the changes or modifications will be incorporated into the legally marketed version of the device prior to marketing and documented in the design history file in accordance with design controls. In addition, you should assess whether these modifications might impact other aspects of the device performance (e.g., biocompatibility) and provide information in the device description section of the submission to demonstrate that the modifications would have no impact on the other aspects or that the modified device was used for the other performance tests.

Additional information not outlined above may be requested by FDA depending on intended use and intended use environment for specific active medical devices (e.g., implantable portions of active devices) to demonstrate the device's claims regarding electromagnetic compatibility (EMC).