Guidance for Industry, FDA Reviewers/Staff and Compliance

Guidance Document for Powered Muscle Stimulator 510(k)s

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This document supersedes documents entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Muscle Stimulators, and Ultrasound Diathermy and Muscle Stimulators," dated July 26, 1995; "Electrical Muscle Stimulator (EMS) Labeling Indications, Contraindications, Warnings, etc.," dated July 11, 1985; and "Technological Reporting for Powered Muscle Stimulator 510(k) Submissions," dated January 1, 1993.



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

Restorative Devices Branch
Division of General and Restorative Devices
Office of Device Evaluation

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to the Restorative Devices Branch, HFZ-410, 9200 Corporate Blvd., Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact the Restorative Devices Branch at 301-594-1296.

Additional Copies

World Wide Web/CDRH home page at http://www.fda.gov/cdrh/ode/2246.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2246 when prompted for the document shelf number.

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Guidance[1] Document for Powered Muscle Stimulator 510(k)s

INTRODUCTION

This guidance document replaces documents entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Muscle Stimulators, and Ultrasound Diathermy and Muscle Stimulators," dated July 26, 1995; "Electrical Muscle Stimulator (EMS) Labeling Indications, Contraindications, Warnings, etc.," dated July 11, 1985; and "Technological Reporting for Powered Muscle Stimulator 510(k) Submissions," dated January 1, 1993. The purpose of developing this new document is to provide the sponsor and FDA reviewers/staff with updated and consolidated guidance regarding powered muscle stimulators identified and classified under 21 CFR 890.5850 and reviewed under the premarket notification [510(k)] process. This guidance also serves to correct erroneous and outdated information contained in the previous guidance documents.

The objective of this document is to identify important administrative, descriptive, and technical information that should be included in a 510(k) submission for a powered muscle stimulator. Individual 510(k) submissions may need additional information pertinent to each specific device. The suggestions and recommendations included in the guidance reflect the typical minimal information that would allow an evaluation of the device, as determined by the Restorative Devices Branch (REDB). Although the use of this document in the preparation of a 510(k) premarket notification will not ensure FDA's granting marketing clearance of a particular device, following the guidance will help ensure that sufficient basic information is available to initiate a substantive review.

This guidance document should be viewed as a "living" document. Accordingly, it will be revised periodically as scientific knowledge and/or regulations change.

All FDA publications referred to in this guidance document can be obtained by contacting the Division of Small Manufacturers Assistance (DSMA) at 800-638-2041 (toll free) or 301-443-6597. Some publications can be obtained via DSMA's Internet site at http://www.fda.gov/cdrh/dsma/dsmamain.html . Specific questions and clarification regarding this guidance document should be directed to the Restorative Devices Branch at 301-594-1296.

[1]This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

ADDITIONAL SOURCES OF INFORMATION

Full-text searches of the Code of Federal Regulations (CFR) can be accessed online by entering the CFR title, part and section numbers, e.g., 21 CFR 807.87, into the online database at: http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html#page1

Questions or comments regarding this online CFR database service should be directed to the Government Printing Office (GPO) Access User Support Team by Internet e-mail at gpoaccess@gpo.gov; by telephone at (202) 512-1530 or toll free at (888) 293-6498; or by fax at (202) 512-1262.

Additional specific topics relating to medical device regulations, policies, and guidance can be accessed under the alphabetical Topic Index on the CDRH home page located at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/topicindex/topindx.cfm

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510(k) SUBMISSION CONTENT

Any 510(k) submitted under premarket notification procedures described in 21 CFR Part 807, Subpart E, for FDA's determination that a new device is substantially equivalent to a legally-marketed predicate (existing) device identified and classified under 21 CFR 890.5850 (Powered Muscle Stimulator), should follow the format below and should contain all specified information that is applicable to the device.

A description of general information to be contained in each premarket notification submission is described in 21 CFR 807.87. Additional information relating specifically to premarket notifications can be accessed by searching in the Topic Index under "P" for Premarket Notification.
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In addition, a copy of the 510(k) manual entitled, "Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices" (HHS Publication FDA 95-4158) can be obtained by contacting DSMA, or via Internet at: http://www.fda.gov/cdrh/manual/510kprt1.html

ADMINISTRATIVE AND GENERAL INFORMATION

The sponsor should provide the following administrative and general information:

1. A table of contents and continuous pagination of the submission and all appendices or attachments;

2. The name and address of both the device manufacturer and sponsor of the 510(k) submission;

3. Identification of the official contact person for all correspondence;

4. The FDA establishment registration number (if available) of the 510(k) sponsor;

5. The proprietary name of the new device, including name and model number, if applicable;

6. The generic name (and/or classification name) of the device, e.g., Powered Muscle Stimulator;

7. The panel code and product code for the device. (The panel code for Physical Medicine devices is 89, and the product code for Powered Muscle Stimulators is IPF);

8. The proposed regulatory class for the new device, e.g., Class II. (21 CFR Part 890 contains the regulatory classifications for Physical Medicine devices);

9. Identification of the existing legally-marketed predicate device to which substantial equivalence is claimed;

10. The classification of the predicate device, e.g., Class II;

11. A description of whether the proposed device:

    a. Has been previously submitted to the FDA for identical or different indications;

    b. Is currently being reviewed for different indications by the same or different branch within ODE; or

    c. Has been previously cleared by the FDA for different indications;

12. Actions taken to comply with the requirements of section 514 of the act, regarding compliance with applicable performance standards, in accordance with 21 CFR 807.87(d);

13. A "510(k) Summary" as described in 21 CFR 807.92 or a "510(k) Statement" as described in 21 CFR 807.93, in accordance with 21 CFR 807.87(h);

14. A financial certification or disclosure statement (applicable to all 510(k) submissions containing references to clinical study data), in accordance with 21 CFR 807.87(i);

15. A "Truthful and Accurate Statement," signed by a responsible person of the firm required to submit the premarket notification, in accordance with 21 CFR 807.87(k); and

16. An "Indications for Use" enclosure should be provided on a separate sheet of paper which lists the device name and clearly identifies the specific indications for use for which a determination of substantial equivalence is sought.

DESCRIPTIVE INFORMATION

INTENDED USE AND INDICATIONS FOR USE

The sponsor should identify and describe the proposed intended use of the device.

The specific intended use(s), including the specific therapeutic indications, for the subject device and the predicate device should be identified. The new device should have the same intended medical uses as those specified for the predicate device, to the extent that the changes do not alter the therapeutic or diagnostic effect and do not affect the safety and effectiveness. These intended uses should be consistent with the descriptions of intended medical uses contained within the CFR section that is applicable to the device and should identify the specific medical conditions for which the device is indicated. If the indication differs from the predicate device, all differences should be identified and a justification as to how the change(s) do not affect safety and effectiveness should be provided. If special labeling claims are sought, information should be provided to support these claims.

The standard indications for use for Powered Muscle Stimulators classified under 21 CFR 890.5850 are:

1. Relaxation of muscle spasms;

2. Prevention or retardation of disuse atrophy;

3. Increasing local blood circulation;

4. Muscle re-education;

5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and

6. Maintaining or increasing range of motion.

A 510(k) submission for a powered muscle stimulator may seek marketing clearance for all of these indications for use, or for a subset of these indications.

Note: Some devices contain multiple operating modes, with each mode having a unique set (or subset) of indications for use. If this is the case for the proposed device, the sponsor should clearly specify (i.e., in both the 510(k) submission and in the labeling) the particular set of indications for use that corresponds to each mode of operation.

Note: In general, muscle stimulators that operate continuously (or without a sufficient period of rest between pulse trains) and/or at an effective frequency above the physiological range may be appropriate only for relaxation of muscle spasms. For such devices, additional information should be provided to support any of the other indications for which repeated, sustainable muscle contractions are necessary to achieve the desired therapeutic effect.

LABELING

The sponsor should provide a complete copy of all labels, labeling, as well as all available promotional and advertising materials. Please refer to Attachment I for additional guidance concerning labeling of powered muscle stimulators.

DEVICE DESCRIPTION

The sponsor should provide a complete description of the proposed device and accessories and a comparison to the legally-marketed predicate device. This description and comparison should include the following general information:

1. A written description of the proposed device, including all device accessories, and any new features of the device;

2. Identification of the relevant dimensions and weight of the device and accessories;

3. A description of all user controls, displays, and functions;

4. A description of how the device interconnects with other components;

5. Engineering drawings and/or photographs of the device; and

6. A detailed table comparing all of the relevant features and specifications of the proposed and predicate devices. This side-by-side comparison table should be accompanied by a discussion of all similarities and differences between the devices and should be sufficiently detailed to provide a basis for a potential determination of substantial equivalence.

Additional descriptive information specific to powered muscle stimulators should be provided. Please refer to Attachment II for guidance concerning the recommended content and format for reporting technological characteristics of powered muscle stimulators.

ATTACHMENTS

Attachment I: Labeling Guidance for Powered Muscle Stimulators

Attachment II: Guidance for Reporting Technological Characteristics of Powered Muscle Stimulators

Attachment I

Labeling Guidance for Powered Muscle Stimulators

General Labeling Guidance

General labeling requirements for medical devices have been established in 21 CFR Part 801. Proposed labels, labeling, advertising and/or promotional materials, and specifications sufficient to describe the device, its intended use and directions for use should be provided. If the device or its accessories is reusable, instructions for maintenance, storing, cleaning, and/or disinfection should be included in the device labeling.

Copies of the following additional general labeling guidance documents may be obtained from the Division of Small Manufacturers Assistance (DSMA) at 1-800-638-2041, or copies may obtained via the Internet at the following addresses:

ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991:
http://www.fda.gov/cdrh/g91-1.html

"Medical Device Labeling: Suggested Format and Content," dated April 25, 1997:
http://www.fda.gov/cdrh/ode/labeling.pdf

"Labeling: Regulatory Requirements for Medical Devices," HHS Publication number FDA 89-4203, dated August, 1989:
http://www.fda.gov/cdrh/dsma/470.pdf

Specific Labeling Guidance for Powered Muscle Stimulators

PRESCRIPTION STATEMENT

Powered Muscle Stimulators regulated under 21 CFR 890.5850 are regarded as prescription devices. Prescription devices must be labeled prominently with the following prescription statement (both on the device label itself and in the labeling, including the user manual and any advertising and promotional materials), in accordance with 21 CFR 801.109:

> "*Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device."*

USER MANUAL

A user manual should be provided. In addition to the prescription statement described above, a complete manual should include, but not be limited to, the following information:

1. A description of the device and all accessories;
2. Illustrations of the device and accessories;
3. A description of all features, functions, output modalities, and specifications;
4. A description of all user-accessible controls;
5. Indicators, markings, and/or labels on the device which provide information regarding the function or meaning of each control, display, output jack, etc.;
6. A description of the size and type of electrodes to be used with the device;
7. Directions for use;
8. Cleaning and/or maintenance instructions, if appropriate; and
9. Appropriate statements of indications, contraindications, warnings, precautions, and adverse reactions, as described in detail below.

The remainder of this labeling guidance lists statements that should be included prominently in the labeling for powered muscle stimulators. These statements address the indications, contraindications, warnings, precautions, and adverse effects associated with the use of powered muscle stimulators:

INDICATIONS FOR USE

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

CONTRAINDICATION

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

WARNINGS

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.

PRECAUTIONS

1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
    a. When there is a tendency to hemorrhage following acute trauma or fracture;
    b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
    c. Over the menstruating or pregnant uterus; and
    d. Over areas of the skin which lack normal sensation.
5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7. Powered muscle stimulators should be kept out of the reach of children.
8. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
9. [FOR PORTABLE DEVICES ONLY]: Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

ADVERSE REACTIONS

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Attachment II

Guidance for Reporting Technological Characteristics of Powered Muscle Stimulators

Introduction

This attachment is intended to provide guidance regarding information that should be included in a 510(k) submission for a powered muscle stimulator, regulated under 21 CFR 890.5850, in order to document the technological characteristics of the new device and to compare the new device's characteristics to those of the identified legally-marketed predicate device. The documentation that should be provided includes, but is not limited to, the following:

Section 1: Output Waveforms
Section 2: Basic Unit Characteristics
Section 3: Output Specifications
Section 4: Description of Accessories
Section 5: Description of Software/Firmware/Microprocessor Control

In addition, the submission should include a description of all similarities and differences between the new device and the predicate device. Ideally, the submission should also contain a table or tables that compare the Basic Unit Characteristics and Output Specifications of the two devices, as outlined in sections 2 and 3 of this attachment.

Section 1: Output Waveforms

For each output mode, a minimum of four oscilloscope tracings (or accurate diagrams) describing the electrical output waveform should be provided. Tracings should be provided to clearly illustrate both individual pulse and pulse burst characteristics. For each output mode, three tracings should be provided to describe the individual pulse output waveform under loads of 500, 2k, and 10k ohms. In addition, for each output mode, one tracing should be provided showing a series of pulses (i.e., pulse burst or pulse train) under a 500 ohm load. The following information should be included with each tracing:

a. the name of the output mode;
b. clearly labeled amplitude and time axes;
c. identification of the amplitude baseline;
d. a list of all output parameter settings (e.g., amplitude, pulse width, frequency, etc.); and
e. the load resistance (in ohms).

Section 2: Basic Unit Characteristics

This section is intended to describe basic unit characteristics. The parameters listed are assumed to be independent of the selected output mode. If this is not the case, or if the information is not applicable to the device, an explanation should be provided. If a specific parameter is not applicable (N/A), this should be noted.

	New Device	**Predicate Device**
1. 510(k) Number	(To Be Assigned)	K_____
2. Device Name, Model	_____	_____
3. Manufacturer	_____	_____
4. Power Source(s)[1]		
- Method of Line Current Isolation		
- Patient Leakage Current[2]		
- Normal condition	_____ µA	_____ µA
- Single fault condition	_____ µA	_____ µA
5. Number of Output Modes[3]		
6. Number of Output Channels[4]		
- Synchronous or Alternating?		
- Method of Channel Isolation		
7. Regulated Current or Regulated Voltage?		
8. Software/Firmware/Microprocessor Control?	Yes / No	Yes / No
9. Automatic Overload Trip?	Yes / No	Yes / No
10. Automatic No-Load Trip?	Yes / No	Yes / No
11. Automatic Shut Off?	Yes / No	Yes / No
12. Patient Override Control?	Yes / No	Yes / No

13. Indicator Display:		
- On/Off Status?	Yes / No	Yes / No
- Low Battery?	Yes / No	Yes / No
- Voltage/Current Level?	Yes / No	Yes / No
14. Timer Range (minutes)		
15. Compliance with Voluntary Standards?	(If yes, specify)	(If yes, specify)
16. Compliance* with 21 CFR 898? (*Becomes mandatory beginning May 9, 2000)	Yes / No	Yes / No
17. Weight		
18. Dimensions (in.) [W x H x D]		
19. Housing Materials and Construction		

Section 2 Notes:

[1]Power Source: For AC line-powered devices, specify line voltage and frequency, method of line current isolation, and measured patient leakage current; for battery-powered devices, specify number, size and type of batteries.

[2]Leakage Current: Patient leakage current should be measured under both normal conditions and under single fault conditions and should be no greater than 100 microamperes and 500 microamperes, respectively. The method of testing should be described, e.g., IEC 601-1.

[3]Output Modes: For devices with more than one output mode, the information in Section 1 and Section 3 should be completed for each output mode.

[4]Output Channels: For devices with more than one output channel, describe whether the outputs are delivered in a synchronous and/or alternating fashion, and describe the method of achieving channel isolation.

Section 3: Output Specifications

An output mode is defined (for reporting purposes) as a version of a waveform produced by the unit. For example, biphasic symmetrical, biphasic asymmetrical, and monophasic would all be considered separate output modes. A copy of the following information should be completed for each output mode. If a specific parameter is not applicable (N/A), this should be noted.

	New Device	**Predicate Device**
Waveform (e.g., pulsed monophasic, biphasic)		
Shape (e.g., rectangular, spike, rectified sinusoidal)		
Maximum Output Voltage (specify units) (+/-_____%)	_____ @ 500 Ω _____ @ 2 kΩ _____ @ 10 kΩ	_____ @ 500 Ω _____ @ 2 kΩ _____ @ 10 kΩ
Maximum Output Current (specify units) (+/-_____%)	_____ @ 500 Ω _____ @ 2 kΩ _____ @ 10 kΩ	_____ @ 500 Ω _____ @ 2 kΩ _____ @ 10 kΩ
Pulse Width[5] (specify units)		
Frequency[5] (Hz)		
For interferential modes only: - Beat Frequency[5] (Hz)		
For multiphasic waveforms only: - Symmetrical phases?	Yes / No	Yes / No
- Phase Duration[5] (include units) (state range, if applicable) (both phases, if asymmetrical)		
Net Charge (μC per pulse) (If zero, state method of achieving zero net charge.)	_____ @ 500 Ω	_____ @ 500 Ω
Maximum Phase Charge, (μC)	_____ @ 500 Ω	_____ @ 500 Ω
Maximum Current Density[6], (mA/cm²)	_____ @ 500 Ω	_____ @ 500 Ω
Maximum Power Density[6], (W/cm²) (using smallest electrode conductive surface area)	_____ @ 500 Ω	_____ @ 500 Ω

	New Device	**Predicate Device**
Burst Mode[7] (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]		
ON Time (seconds)		
OFF Time (seconds)		
Additional Features (if applicable)		

Section 3 Notes:

[5]Variable Parameters: For continuously variable parameters, specify the full range; for parameters with discrete settings, specify all available selections.

[6]Density Measurements: Maximum current density and power density values should be calculated using the conductive surface area of the smallest electrodes provided/recommended for use with the unit; sample calculations should be provided. The maximum power density should be based on the maximum duty cycle and should be averaged over an output duration of one second. The maximum power density should be less than 0.25 Watts/cm^2 to reduce the risk of thermal burns.

[7]Burst Mode: For effectiveness in achieving repeated muscle contractions, powered muscle stimulators typically are capable of stimulating muscle for at least one second per burst, and are capable of providing at least one second of muscle relaxation between successive pulse bursts.

Section 4: Description of Accessories

All relevant technological characteristics should be listed and described for each device accessory. For any accessories that have received prior marketing clearance, the sponsor should identify the name of the manufacturer and provide reference to the 510(k) number through which marketing clearance was obtained. For any new accessories, the sponsor should include the following information:

1. Electrodes
   The type and size of all available and recommended electrodes should be specified. If a new material is used, the chemical composition of the adhesive material should be identified, and sensitization and irritation data should be provided. If the materials are substantially equivalent to a legally-marketed electrode, the sponsor should provide identification of the legally-marketed device (including 510(k) number), and a description of similarities and differences.

2. Electrode Conductive Medium (Gel)
   If the electrodes are to be used with a conductive medium, the sponsor should provide the same type of information as described above for the electrode adhesive material.

3. Electrode Lead Wires and Patient Cables
   The sponsor should describe the length(s), construction, materials, and connections between the stimulator device and the electrodes. Sponsor should be aware that electrode lead wires and patient cables intended for use with a medical device are subject to the mandatory performance standard set forth in 21 CFR Part 898. Please refer the Additional Information section at the end of this guidance for further details.

4. Batteries
   The sponsor should identify the number, size, and type of batteries to be used with the device.

5. Battery Charger
   If the device can be used with rechargeable batteries, the sponsor should identify the method used to isolate the user from AC line current, and should provide the patient leakage current under both normal and single fault conditions, as described in Section 2 above.

Section 5: Description of Software/Firmware/Microprocessor Control

The document entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 29, 1998, provides general guidance on this subject. This guidance document may be obtained from DSMA or via the Internet at: http://www.fda.gov/cdrh/ode/software.pdf.

For powered muscle stimulators controlled by software (or firmware or a microprocessor), the sponsor should include the following information at a minimum:

1. Determination of the level of concern;

2. Description of all device functions controlled by the software;

3. Hazard analysis;

4. Software functional requirements;

5. Description of the system-level test protocol, including pass/fail criteria; and

6. Summary of the test results.

Additional Information

1. **Electrode Lead Wires and Patient Cables**

Electrode lead wires and patient cables intended for use with a medical device are subject to the mandatory performance standard set forth in 21 CFR Part 898. For electrode lead wires and patient cables used with, or intended for use with, Powered Muscle Stimulators, the date for which compliance with this standard is required is May 9, 2000.

More information about this performance standard can be found on the CDRH Home page at http://www.fda.gov/cdrh/topindx.html by searching in the Topic Index under "L" for Lead Wires.

Letter to User Facilities Regarding Lead Wires and Patient Cables
http://www.fda.gov/cdrh/comp/leadwireletter.html

Guidance Document on the Performance Standard for Electrode Lead Wires and Patient Cables
http://www.fda.gov/cdrh/comp/leadwire.html

FDA Talk Paper: FDA Sets New Safety Requirement for Cables and Leads
http://www.fda.gov/bbs/topics/ANSWERS/ANS00796.html

Federal Register: Medical Devices; Establishment of a Performance Standard for Electrode Lead Wires and Patient Cables
http://www.fda.gov/cdrh/comp/fr0509af.html

2. **Electromagnetic Compatibility (EMC)**

At the time this document was written, the Agency's position on EMC for powered muscle stimulators was that documentation of electromagnetic compatibility of powered muscle stimulators in their operating environment is not a regulatory requirement. However, if a specific EMC claim is made in labeling or in promotional/advertising materials at the time of the 510(k) submission, this claim should be supported by valid scientific evidence.

Additional information relating to EMC can be found on the CDRH Home Page at http://www.fda.gov/cdrh/topindx.html by searching in the Topic Index under "E" for Electromagnetic Compatibility.