Draft Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Powered Muscle Stimulator for Rehabilitation

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
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Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.
When final, this document will supersede Guidance Document for Powered Muscle Stimulator 510(k)s, issued June 9, 1999.

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

Restorative Devices Branch
Division of Surgical, Orthopedic and Restorative Devices
Office of Device Evaluation

Preface

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198793.htm. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1577) to identify the guidance you are requesting.

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Class II Special Controls Guidance Document: Powered Muscle Stimulator for Rehabilitation

1. Introduction

This draft guidance document was developed as a special controls guidance for powered muscle stimulators that are indicated for rehabilitation. If proposed 21 CFR 890.5850(a) is finalized, a powered muscle stimulator for rehabilitation will be defined as an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing pulsed electrical current through cutaneous electrodes contacting the affected body area. We consider this intended use to include use as an adjunctive therapy in rehabilitation for medical purposes such as relaxation of muscle spasm, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

This draft guidance is being issued in conjunction with a Federal Register notice announcing a proposal to designate a special controls guidance for this device type.[1] This guidance is issued for comment purposes only. If a final rule designating this guidance as a special control for this device type is not issued, then this guidance document will not be issued in final form.

Following the effective date of a final rule, any firm submitting a 510(k) for a powered muscle stimulator for rehabilitation will need to address the issues covered in the special controls guidance. The firm must show in its 510(k) that its device meets the requirements of 21 CFR 807.87 and complies with the special controls, either by following the recommendations of the guidance or in some other way providing equivalent assurances of safety and effectiveness.

Presently there is in effect a guidance document entitled, **Guidance Document for Powered Muscle Stimulator 510(k)s**.[2] The 1999 guidance document is applicable to powered muscle stimulators used for rehabilitation. If proposed 21 CFR 890.5850(a) is finalized, FDA will withdraw the 1999 guidance and replace it with this special controls guidance.

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[1] In addition to proposing to designate a special controls guidance for this device type, the proposed rule would also designate as a special control sale, distribution, and use restricted to prescription use in accordance with 21 CFR 801.109.

[2] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073782.htm.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the powered muscle stimulator for rehabilitation. Thus, a manufacturer who intends to market a device of this generic type must: (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the specific issues associated with the powered muscle stimulator for rehabilitation identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device (section 513(a)(1)(B) of the act; 21 USC 360c(a)(1)(B)).

This special controls guidance document identifies the classification regulation and product code for the powered muscle stimulator for rehabilitation. In addition, other sections of this special controls guidance document list the issues requiring special controls identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the issues associated with the powered muscle stimulator for rehabilitation and lead to a timely review of premarket notification submissions. This document supplements other FDA documents regarding the content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87 and the guidance entitled, **Format for Traditional and Abbreviated 510(k)s**.[3]

As described in the guidance entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**,[4] a manufacturer may submit a Traditional 510(k) or, under some circumstances, has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) often provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA issues a class II special controls guidance document. Manufacturers considering certain modifications to their own cleared devices may, in many instances, lessen the regulatory burden by submitting a Special 510(k).

3. Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special controls guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the issues identified in this document, as well as any additional issues

[3] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm.

[4] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm.

specific to your device. This section suggests information to fulfill some of the requirements of 21 CFR 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Please refer to **Section 8 - Labeling** for specific information that should be included in the labeling for devices of the type covered by this guidance document.)

Summary report

We recommend that the summary report contain the following:

Description of the device and its intended use

We recommend that you describe the performance specifications and, when appropriate, include detailed, labeled drawings of the device. (Please refer to **Section 5 - Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You also should submit an "indications for use" enclosure.[5]

Description of device design

We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method

We recommend that you identify the risk analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Please refer to **Section 6 - Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.)

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the issues identified in this class II special controls guidance document, and any additional issues specific to your device, including additional risks identified in your risk analysis.

Description of the performance aspects

We recommend that you include a brief description of the test method(s) you have used

[5] For the recommended format, refer to *Indications for Use Form, available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080276.htm.

or intend to use to address each performance aspect identified in **Section 7 - Performance Characteristics** of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either: (1) briefly present the data resulting from the test in clear and concise form, such as a table, or (2) describe the acceptance criteria that you will apply to your test results.[6] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

Reliance on standards

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either of the following:

- a statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- a declaration of conformity to the standard.[7]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**.[8]

If it is not clear how you have addressed the issues identified by FDA, additional issues specific to your device, or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

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[6] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[7] See "Required Elements for a Declaration of Conformity to a Recognized Standard" (Screening Checklist for All Premarket Notification [510(k)] Submissions), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm.

[8] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm.

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting a Special 510(k).

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification submission for a powered muscle stimulator for rehabilitation.

4. Scope

The scope of this document is limited to the device identified in proposed section 890.5850(a) and described below.

> Section 890.5850(a) Powered muscle stimulator for rehabilitation—
>
> Identification. A powered muscle stimulator for rehabilitation is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing pulsed electrical current through cutaneous electrodes contacting the affected body area. This does not include the powered muscle stimulators classified in paragraphs (b)-(d) of this section.

The powered muscle stimulator for rehabilitation should be intended for use as an adjunctive therapy in rehabilitation for medical purposes such as relaxation of muscle spasm, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. Powered muscle stimulators for rehabilitation have been assigned product code IPF.

Classification Regulation	Device Type Addressed by this Guidance Document	Product Code
890.5850(a)	Powered muscle stimulator for rehabilitation	IPF

If a powered muscle stimulator is intended for another use, such as in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the human body other than as described in this document, that powered muscle stimulator is beyond the scope of this guidance document. Powered muscle stimulators marketed for such additional intended uses may be subject to additional regulatory requirements, including premarket approval (section 515 of the act; 21 USC 360e).

FDA is also issuing draft special controls guidance documents for other similar device types summarized in the table below. If a final rule designating special controls guidance documents for each of these device types is issued, you should refer to section 890.5850 and the special

controls guidance documents to determine which guidance document is appropriate for your device based on its intended use and technological characteristics. The following device types have intended uses or technological characteristics that are not addressed by this guidance document:

Classification Regulation	Device Types not Addressed by this Guidance Document	Product Code
890.5850(b)	Powered muscle stimulator with limited output for rehabilitation	NYY
890.5850(c)	Powered muscle stimulator for muscle conditioning	NGX
890.5850(d)	Powered muscle stimulator with limited output for muscle conditioning	NYZ

5. Device Description

You must provide a device description in your 510(k), 21 CFR 807.92(a)(4). We recommend that the device description section include the following information:

- identification of the device, by the regulation number and product code described in **Section 4 - Scope**
- a written description of the device, including all device accessories
- identification of the relevant dimensions and weight of the device and accessories
- a description of all user controls, displays, and functions
- a list of all available output modes or programs and a summary of the specific indications for use associated with each mode or program
- a description of how the device interconnects with other components or accessories
- engineering drawings and/or photographs of the device
- a detailed listing, for example in a tabular format, of all the relevant features and specifications of the device.

Additional descriptive information specific to the performance characteristics for powered muscle stimulators for rehabilitation should be provided, as described in **Section 7 - Performance Characteristics**.

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the powered muscle stimulator for rehabilitation. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. We

recommend that you conduct a risk analysis to identify any other risks specific to your device and include the results of this analysis in your submission. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	Recommended mitigation measures
Electrical hazards that may result in user discomfort or injury	Sections 7 and 8
Adverse reactions to the skin-contacting materials	Sections 7 and 8

7. Performance Characteristics

In accordance with 21 CFR 807.87, we recommend that you include the following information in your 510(k) to document your device's performance characteristics and to compare your device's characteristics to those of the identified legally marketed predicate device.

A. Output Waveforms

For each output mode, defined in Section C below, we recommend that you include oscilloscope tracings (or accurate diagrams) in your 510(k) to describe your device's electrical output waveform and to clearly illustrate both individual pulse and pulse burst characteristics. These tracings should use time and voltage scales sufficient to graphically represent the amplitude (i.e., voltage) and temporal characteristics of both individual pulses and pulse bursts, as applicable. Note that to adequately graphically characterize complex waveforms, such as those involving a pulse duration that is significantly shorter than the interpulse interval or burst duration, you should generally include separate oscilloscope tracings using different time scales. For example, the graphical representation of a repeating burst of pulses may consist of one tracing with a shorter time scale that characterizes the pulse characteristics and a second tracing with a longer time scale that characterizes the burst characteristics. You should include three tracings to describe the individual pulse output waveform under loads of 500, 2k, and 10k ohms, and one tracing to illustrate a series of pulses (i.e., pulse burst or pulse train) under a load of 500 ohms. Each tracing should include the following:

- the name of the output mode
- clearly labeled amplitude and time axes, with appropriate scales (i.e., volts per division and time per division)
- identification of the amplitude baseline
- a list of all output parameter settings, e.g., amplitude, pulse duration, frequency
- the load resistance, in ohms.

You should include additional tracings for any complex waveforms that cannot be adequately characterized using the four tracings described above.

B. Basic Unit Characteristics

We recommend that you include in your 510(k) a section that describes your device's basic unit characteristics and compares them to the predicate device's characteristics. The parameters listed in this section are assumed to be independent of the selected output mode. If this is not the case, or if you believe any of the listed parameters are not applicable to your device, we recommend that you include an explanation. A tabular format is desirable, as shown in the example below.

Parameter		Your Device	Predicate Device
510(k) Number		(to be assigned)	
Device Name and Model			
Manufacturer			
Power Source(s)†			
- Method of Line Current Isolation			
- Patient Leakage Current††		---	---
- Normal Condition (μA)			
- Single Fault Condition (μA)			
Average DC current through electrodes when device is on but no pulses are being applied (μA)			
Number of Output Modes †††			
Number of Output Channels ††††:	Synchronous or Alternating?		
	Method of Channel Isolation		
Regulated Current or Regulated Voltage?			
Software/Firmware/Microprocessor Control?		Yes / No	Yes / No
Automatic Overload Trip?		Yes / No	Yes / No
Automatic No-Load Trip?		Yes / No	Yes / No
Automatic Shut Off?		Yes / No	Yes / No
User Override Control?		Yes / No	Yes / No
Indicator Display:	On/Off Status?	Yes / No	Yes / No
	Low Battery?	Yes / No	Yes / No
	Voltage/Current Level?	Yes / No	Yes / No
Timer Range (minutes)			
Compliance with Voluntary Standards?		If yes, specify.	If yes, specify.
Compliance with 21 CFR 898[9]?		Yes / No	Yes / No
Weight (lbs., oz.)			
Dimensions (in.) [W x H x D]			
Housing Materials and Construction			

† For AC line-powered devices, we recommend that you specify the line voltage and frequency, the method of line current isolation, and the measured patient leakage current. For battery-powered devices, we recommend that you specify the number, size, and type of batteries.

[9] The 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. See "Electrode Lead Wires and Patient Cables" in Section F, below.

[††] We recommend that you follow IEC 60601-1, *"Medical Electrical Equipment - Part 1: General Requirements for Safety"* or an equivalent method to show that patient leakage current, under both normal and single fault conditions, is acceptable.

[†††] For devices with more than one output mode, we recommend that you provide the information in Output Waveforms (see Section 7A above) and Output Specifications (see Section 7C below) for each output mode.

[††††] For devices with more than one output channel, we recommend that you describe whether the outputs are delivered in a synchronous and/or alternating fashion and the method of achieving channel isolation.

C. Output Specifications

For the purpose of this document, an output mode is defined as a version of a waveform produced by the unit. For example, we consider biphasic symmetrical, biphasic asymmetrical, and monophasic to be separate output modes. We also consider each unique, preset combination of stimulation parameters (sometimes referred to as a "program") to constitute a distinct output mode. For example, if a device offers the user the ability to choose between "Program 1," consisting of a monophasic waveform with a specific range of output voltages, pulse durations, frequencies, etc., "Program 2," consisting of a monophasic waveform with a different range of output voltages, pulse durations, frequencies, etc., and "Program 3," consisting of a biphasic waveform, this device would be considered to have three output modes. Devices sometimes have unique indications for use or intended uses associated with each output mode. To enable a meaningful analysis, all technological comparisons between your device and the identified predicate device should be for the same intended uses and indications for use. Comparisons of output specifications between devices or output modes having different indications for use is generally not recommended because such comparisons are of limited value in demonstrating substantial equivalence. We recommend that you provide the following information separately for each output mode. We also recommend that you identify any parameters that are not applicable to your device. A tabular format, presented separately for each output mode, is desirable, as shown in the example below.

Parameter	**Your Device**	**Predicate Device**
Mode or Program Name		
Waveform (e.g., pulsed monophasic, biphasic)		
Shape (e.g., rectangular, spike, rectified sinusoidal)		
Maximum Output Voltage (volts) (+/- ____%)	____@500 Ω	____@500 Ω
	____@ 2 kΩ	____@ 2 kΩ
	____@10 kΩ	____@10 kΩ
Maximum Output Current (specify units) (+/- ____%)	____@500 Ω	____@500 Ω
	____@ 2 kΩ	____@ 2 kΩ
	____@10 kΩ	____@10 kΩ
Duration of primary (depolarizing) phase[†] (μsec)		
Pulse Duration[†] (μsec)		
Frequency[†] (Hz) [or Rate[†] (pps)]		

Parameter		**Your Device**	**Predicate Device**
For interferential modes only: Beat Frequency† (Hz)			
For multiphasic waveforms only:	Symmetrical phases?	Yes / No	Yes / No
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)		
Net Charge (microcoulombs (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,†† (mA/cm², r.m.s.)		_____@500 Ω	_____@500 Ω
Maximum Average Current (average absolute value), mA		_____@500 Ω	_____@500 Ω
Maximum Average Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		_____@500 Ω	_____@500 Ω
Burst Mode††† (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 (specify, if applicable)			

† For continuously variable parameters, we recommend that you specify the full range; for parameters with discrete settings, we recommend that you specify all available selections.

†† We recommend that you calculate the maximum current density and maximum average power density values by using the conductive surface area of the smallest electrodes intended for use with the unit, and include sample calculations in your 510(k). We also recommend that you calculate the maximum power density by using the maximum duty cycle and by averaging over an output duration of one second. The maximum average power density should be less than 0.25 watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns.

††† 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.

D. Device Safety

To mitigate the risks to health identified above, we recommend that you conduct appropriate device safety testing. You should consider the following as part of your device safety testing and you should include a summary of this testing in the 510(k).

- For AC-powered devices, patient leakage current should be at an acceptable level. You should measure patient leakage current under both normal and single fault conditions. We recommend that you follow the FDA-recognized standard, IEC 60601-1, *"Medical Electrical Equipment - Part 1: General Requirements for Safety"*

or an equivalent method to show that the measured levels of patient leakage current are acceptable.

- The output of the stimulus generator should be controlled by appropriately marked knobs, dials, switches, indicators, etc., and these controls should modulate output intensity in a smooth, incremental, and predictable manner.
- The stimulus generator should not become unsafe if the output is switched on with open-circuited or short-circuited electrodes.
- Power supply voltage fluctuations of ±10 percent should not affect the stimulus generator output amplitude, pulse duration, or pulse repetition frequency (rate) by more than ±10 percent.
- All skin-contacting materials should be biocompatible for their intended use. To determine the applicable device category and tests, you should consult ANSI/AAMI/ISO 10993-1:2003, *"Biological evaluation of medical devices -- Part 1: Evaluation and testing"* or an equivalent method. This FDA-recognized standard recommends evaluation and testing of medical devices based upon the duration and type of contact. For materials with a limited contact duration (e.g., less than 24 hours), we recommend the following tests to establish material safety: dermal irritation, sensitization, and cytotoxicity.

E. Device Effectiveness

In order to provide reasonable assurance of device effectiveness, you should include, in your 510(k), evidence that is sufficient to demonstrate that the device is as effective as the predicate device for its described intended uses, indications for use, and marketing claims. This should include data and analysis that correlate the intended use and the device output parameters with clinical outcome measures that are appropriate to support the intended uses, indications, and claims.

F. Accessories

For each device accessory, your 510(k) should list and describe all relevant technological characteristics. For any accessory that has received prior marketing clearance, we recommend that you identify the name of the manufacturer of the accessory and the 510(k) number. You should also follow the recommendations described below for accessories.

Electrodes

Cutaneous electrodes used with powered muscle stimulators for rehabilitation are regulated as class II devices under 21 CFR 882.1320. FDA is proposing to designate a special control and exempt these cutaneous electrodes from premarket notification requirements under section 510(k) of the act in the proposed rule issued with this draft guidance. See also the draft guidance document entitled, **Class II Special Controls Guidance Document: Cutaneous Electrode**,[10] when finalized, for specific recommendations on the types of information to document for this accessory.

[10] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199247.htm.

Electrode Conductive Medium (Gel)

Electroconductive media used with powered muscle stimulators for rehabilitation are regulated as class II devices under 21 CFR 882.1275. FDA is proposing to designate a special control and exempt these electroconductive media from premarket notification requirements under section 510(k) of the act in the proposed rule issued with this draft guidance. See also the draft guidance document entitled, **Class II Special Controls Guidance Document: Electroconductive Media**,[11] when finalized, for specific recommendations on the types of information to document for this accessory.

Electrode Lead Wires and Patient Cables

We recommend that your 510(k) describe the length(s), construction, materials, and connections between the stimulator device and the electrodes. The 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. The electrode lead wires and patient cables must be in compliance with the test requirements and test methods of subclause 56.3(c) of IEC 601-1 (1998), *"Medical Electrical Equipment - Part 1: General Requirements for Safety,"* Amendment No. 1 (1991), and Amendment No. 2 (1995), see 21 CFR 898.12(a). Your 510(k) should contain information sufficient to demonstrate conformance to this mandatory performance standard.

Batteries

We recommend that your 510(k) identify the number, size, and type of batteries used with the device.

Battery Charger

If the device is intended for use with rechargeable batteries, we recommend that your 510(k) identify the method used to isolate the user from AC line current, and that you follow IEC 60601-1, *"Medical Electrical Equipment - Part 1: General Requirements for Safety"* or an equivalent method to show that the levels of patient leakage current, measured under both normal and single fault conditions, are acceptable.

G. Software/Firmware/Microprocessor Control

For powered muscle stimulators for rehabilitation controlled by software (or firmware or a microprocessor), we recommend you document the appropriate information, based on the level of concern and recommendations described in the guidance document entitled **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices** (the Software guidance)[12] in your 510(k).

See guidance for general information on this subject.

[11] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199256.htm.

[12] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm.

H. Electromagnetic Compatibility (EMC)

If performance characteristics related to EMC are described in your labeling, we recommend that you provide in your 510(k) the valid scientific evidence that supports these performance characteristics.

8. Labeling

The 510(k) must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are intended to help you prepare labeling that satisfies the requirements of 21 CFR Part 801.[13]

Directions for Use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, we recommend submitting clear and concise instructions that delineate the technological features of the specified device and how the device is to be used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

Prescription Statement

In accordance with 21 CFR 801.109, the device label and labeling must bear the caution statement (see 21 CFR 801.109(b)(1)) restricting the device to sale under a prescription order from a licensed practitioner.

Note: This guidance document and, in particular, this labeling section, are not applicable to powered muscle stimulators for rehabilitation that are intended to be sold directly to lay users.

Device User Manual

We recommend that you provide in your 510(k) a copy of the device user manual. In addition to the prescription statement above, the user manual should include descriptions of the following:

- the device and all accessories
- how the device interconnects with other components or accessories
- all features, functions, output modalities, and specifications
- all user-accessible controls
- indicators, markings, and labels on the device, which provide information regarding the function or meaning of each control, display, output jack, etc.
- the size and type of electrodes used with the device, including whether electrodes are interchangeable or replaceable.

[13] Labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance document are consistent with the requirements of 21 CFR Part 801.

The user manual should also contain the following:

- a list of all available output modes or programs and a summary of the specific indications for use associated with each mode or program
- illustrations of the device and accessories
- instructions for storage, cleaning, and maintenance of the device and accessories.

Under 21 CFR 801.109(c), prescription device labeling must include information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the device safely and for the purpose for which it is intended. Therefore, we recommend that the user manual describe the intended use of the device, and include a listing of indications, contraindications, warnings, precautions, and adverse reactions, appropriate to your device. We recommend that you place this information prominently in the device user manual. The labeling recommendations below are not intended to capture all possible limitations or instructions for all powered muscle stimulators for rehabilitation. In preparing your prescription device labeling, it may be necessary for you to include additional information for use (e.g., contraindications, warnings, precautions, adverse reactions, and other instructions) that are appropriate for your device, depending on its specific design, features, and performance characteristics.

Intended Use

The powered muscle stimulators covered by this guidance document are those intended for use in rehabilitation. The intended use of devices of this type, including any indications for use, is limited to use in rehabilitation, including providing adjunctive therapy in rehabilitation for medical purposes. Specific indications for use for powered muscle stimulators that we consider to be for rehabilitation include the following:

- relaxation of muscle spasm
- prevention or retardation of disuse atrophy
- increasing local blood circulation
- muscle re-education
- maintaining or increasing range of motion
- immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

The device should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

If a powered muscle stimulator is intended for another use or indication, such as in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the human body other than as described in this document, then that powered muscle stimulator is beyond the scope of this guidance document. Powered muscle stimulators marketed for other intended uses may be subject to additional regulatory

requirements, including premarket approval (section 515 of the act).

Some devices may contain multiple operating modes, with each mode having a unique indication for use. If this is the case for your device, we recommend that you clearly specify, in the 510(k), on the "Indications for Use" enclosure, and in the labeling, the particular indication for use that corresponds to each mode of operation.

Contraindication

We recommend that the user manual include the following statement:

- Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device because this may cause electric shock, burns, electrical interference, or death.

Warnings

We recommend that the user manual advise users of the following:

- Do not apply stimulation over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
- Do not apply stimulation across the patient's chest because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal;
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
- Do not apply stimulation over, or in proximity to, cancerous lesions;
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use;
- Do not apply stimulation when the patient is in the bath or shower;
- Do not apply stimulation while the patient is sleeping; and
- Do not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.

We also recommend that the user manual advise users of the following:

- Consult with the patient's physician before using this device because the device may cause lethal rhythm disturbances to the heart in susceptible individuals; and
- Apply stimulation only to normal, intact, clean, healthy skin.

Precautions

We recommend that the user manual advise users of the following:

- The long-term effects of electrical stimulation are unknown;
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head;
- The safety of electrical stimulation during pregnancy has not been established;
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium;
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians; and
- Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.

We also recommend that the user manual advise users of the following:

- Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture;
- Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process;
- Use caution if stimulation is applied over the menstruating or pregnant uterus; and
- Use caution if stimulation is applied over areas of skin that lack normal sensation.

The user manual also should advise users of the following:

- Keep this device out of the reach of children;
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer; and
- Use this device only under the continued supervision of a licensed practitioner.

Adverse Reactions

We recommend that the user manual include known adverse reactions as in the examples below:

- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face; and
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.