

Draft Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator with Limited Output for Pain Relief

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.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be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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*.

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

**Ophthalmic Lasers, Neuromuscular Stimulators,
and Diagnostics Branch
Division of Ophthalmic, Neurological, and
Ear, Nose and Throat Devices
Office of Device Evaluation**

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Preface

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1. Introduction

This draft guidance document was developed as a special controls guidance for this class II device and to support the exemption from premarket notification (510(k)) requirements of the Federal Food, Drug, and Cosmetic Act (the act) of transcutaneous electrical nerve stimulators (TENS devices) with limited output that are indicated for pain relief (see sections 510(m) and 513(a)(1)(B) of the act; 21 USC 360(m) and 360c(a)(1)(B)). If proposed 21 CFR 882.5890(c) is finalized, a TENS device with limited output for pain relief will be defined as an electrically powered device that is used to apply an electrical current to electrodes on a patient's skin to relieve pain and conforms to the output limitations of proposed 21 CFR 882.5890(c)(1).

This draft guidance is being issued in conjunction with a Federal Register notice announcing a proposal to designate a special controls guidance and to exempt this device type from the premarket notification requirements of the act if the manufacturer follows the recommendations in the special controls guidance document and meets the prescription device requirements in 21 CFR 801.109.¹ This guidance is issued for comment purposes only. If a final rule is not issued designating this guidance as a special control, then the guidance will not be issued in final form.

This draft guidance document describes a means by which transcutaneous electrical nerve stimulators with limited output for pain relief may comply with the requirement of class II special controls (513(a)(1)(B) of the act). Designation of this guidance document as a special control will mean that manufacturers of transcutaneous electrical nerve stimulators with limited output for pain relief will need to address the issues identified in this special controls guidance

¹ The proposed rule would designate two special controls for this device type: this draft special controls guidance document; and sale, distribution, and use restricted to prescription use in accordance with the prescription device requirements in 21 CFR 801.109. Under the proposed rule, for a device of this type to be exempt from the premarket notification requirements of section 510(k) of the act, the manufacturer would need to both follow the specific measures recommended in this guidance and meet the prescription device requirements in 21 CFR 801.109.

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document. However, if the regulation is finalized designating this guidance as a special control, a manufacturer need only show that its device meets the special controls by following the recommendations of the guidance document or in some other way providing equivalent assurances of safety and effectiveness. Under section 510(m), FDA is also proposing to exempt from the requirement of premarket notification certain devices falling within this classification. If the proposed rule is finalized, manufacturers who follow the specific measures recommended in this guidance and meet the prescription device requirements in 21 CFR 801.109 will be able to market their device without being subject to the premarket notification requirements of section 510(k) of the act, subject to the limitations on exemption in 21 CFR 882.9.² Manufacturers who choose to provide equivalent assurances of safety and effectiveness other than those specified in the draft special controls guidance document when finalized will need to submit a 510(k) and receive marketing clearance for their device.

2. Scope

The scope of this document is limited to the device identified in proposed section 882.5890(c) and described below.

Section 882.5890(c) Transcutaneous electrical nerve stimulator with limited output for pain relief—

(1) Identification. A transcutaneous electrical nerve stimulator with limited output for pain relief is an electrically powered device that is used to apply an electrical current to electrodes on a patient's skin to relieve pain. This does not include the device types classified in paragraphs (a)-(b) and (d)-(f) of this section. The device utilizes a stimulus generator that delivers, into a resistive load, which represents the worse case of either 500 ohms or the typical load expected during normal conditions of use, the following:

- (i) a maximum charge per phase that does not exceed Q , where $Q = 20 + (28)(t)$ microcoulombs (and where t is the phase duration expressed in milliseconds and measured at 50 percent of the phase amplitude);
- (ii) a maximum average current that does not exceed 10 milliamperes (average absolute value);
- (iii) a maximum primary (depolarizing) phase duration that does not exceed 500 microseconds;
- (iv) an average DC current that does not exceed 100 microamperes when no pulses are being applied, or if the device fails;
- (v) a maximum current density that does not exceed 2 milliamperes r.m.s. per square centimeter of electrode conductive surface area; and
- (vi) a maximum average power density that does not exceed 0.25 watts per square centimeter of electrode conductive surface area.

² We recommend that manufacturers document how they address the recommendations of this guidance in their design history file. Manufacturers must maintain design controls, including a design history file, in accordance with [21 CFR 820.30](#).

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The transcutaneous electrical nerve stimulator with limited output for pain relief should be intended for use as an adjunctive therapy for pain management for medical purposes such as symptomatic relief of chronic intractable pain, relief of acute post-surgical and post-traumatic pain, and relief of pain associated with arthritis. For purposes of this guidance, we refer to products subject to this guidance as TENS devices with limited output for pain relief. TENS devices with limited output for pain relief have been assigned product code NYW. TENS devices with limited output for relief of pain associated with arthritis have been assigned product code OCF.

Classification Regulation	Device Type Addressed by this Guidance Document	Product Codes
882.5890(c)	Transcutaneous electrical nerve stimulator with limited output for pain relief	NYW, OCF

If a TENS device with limited output for pain relief 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 TENS device is beyond the scope of this guidance document. Articles marketed for such additional intended uses may be subject to additional regulatory requirements, including premarket notification or premarket approval (sections 510(k) and 515 of the act; 21 USC 360(k) and 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 882.5890 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 <u>not</u> Addressed by this Guidance Document	Product Code(s)
882.5890(a)	Transcutaneous electrical nerve stimulator for pain relief	GZJ, NYN
882.5890(b)	Transcutaneous electrical nerve stimulator for pain relief intended for over the counter use	NUH
882.5890(d)	Percutaneous electrical nerve stimulator for pain relief	NHI
882.5890(e)	Transcutaneous electrical stimulator for aesthetic purposes	NFO

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Classification Regulation	Device Types <u>not</u> Addressed by this Guidance Document	Product Code(s)
882.5890(f)	Transcutaneous electrical stimulator with limited output for aesthetic purposes	NYX

Electrical stimulators for pain relief that have a true (i.e., not premodulated) interferential output mode are considered interferential current therapy devices. Interferential current therapy devices are beyond the scope of this guidance document. If your device is an interferential current therapy device, you should contact FDA regarding applicable regulatory requirements.

3. Risks to Health

In the table below, FDA has identified the following risks to health associated with the use of the TENS device with limited output for pain relief. We recommend the following measures to mitigate the risks identified in this guidance document.

Identified risk	Recommended mitigation measures
Electrical hazards that may result in user discomfort or injury	Sections 5 and 6
Adverse reactions to the skin-contacting materials	Sections 5 and 6

4. Device Description

Under 21 CFR 820.181(a), the device master record must include or reference the following, for each type of device:

- specifications, including appropriate drawings
- composition
- formulation
- component specifications
- software specifications.

Accordingly, we recommend that you maintain a complete description of the device and all accessories in the device master records. This description should include the following:

- identification of the device, by the regulation number and product code described in Section 2 above
- a written description of the device, including all accessories
- identification of the relevant dimensions and weight of the device and accessories

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- 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 tabular format, of the relevant features and specifications of the device.

5. Performance Characteristics

Under the Design Controls section of the Quality System Regulation (21 CFR 820.30), each device manufacturer must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. In meeting the design validation component of these design control requirements, each manufacturer must validate their device design, i.e., establish by objective evidence that device specifications conform to defined user needs and intended uses (21 CFR 820.3(z)(2)). The results of design validation must be documented in the design history file (DHF) (21 CFR 820.30(g)). We recommend that manufacturers evaluate their devices as described below and, where appropriate, document the results in their design history files as a part of the Design Controls requirements (21 CFR 820.30). We recommend that you also maintain the information below in your device master records (21 CFR 820.3(i)) to document your device's specifications and performance characteristics.

A. Output Waveforms

For each output mode, defined in Section C below, we recommend that you maintain oscilloscope tracings (or accurate diagrams) in your device master records 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 maintain 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. This documentation 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)

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- 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 maintain in your device master records a section that describes your device's basic unit 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		Response
Device Name and Model		
Manufacturer		
Number, Size, and Type of Batteries [†]		
Average DC current through electrodes when device is on but no pulses are being applied (μ A)		
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
Automatic Overload Trip?		Yes / No
Automatic No-Load Trip?		Yes / No
Automatic Shut Off?		Yes / No
User Override Control?		Yes / No
Indicator Display:	On/Off Status?	Yes / No
	Low Battery?	Yes / No
	Voltage/Current Level?	Yes / No
Timer Range (minutes)		
Compliance with Voluntary Standards?		If yes, specify.
Compliance with 21 CFR 898? ³		Yes / No
Weight (lb., oz.)		
Dimensions (in.) [W x H x D]		
Housing Materials and Construction		

[†] We recommend that you specify the number, size, and type of batteries.

³ 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.

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†† For devices with more than one output mode, we recommend that you document the information in Output Waveforms (see Section 5A above) and Output Specifications (see Section 5C 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. We recommend that you document 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		Response
Mode or Program Name		
Waveform (e.g., pulsed monophasic, biphasic)		
Shape (e.g., rectangular, spike, rectified sinusoidal)		
Maximum Output Voltage (volts) (+/- ____%)		____ @500 Ω
		____ @2 kΩ
		____ @10 kΩ
Maximum Output Current (specify units) (+/- ____%)		____ @500 Ω
		____ @2 kΩ
		____ @10 kΩ
Duration of primary (depolarizing) phase [†] (μsec)		
Pulse Duration [†] (μsec)		
Frequency [†] (Hz) [or Rate [†] (pps)]		
For multiphasic waveforms only:	Symmetrical phases?	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
Maximum Phase Charge, (μC)		____ @500 Ω
Maximum Current Density ^{††} , (mA/cm ² , r.m.s.)		____ @500 Ω

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Parameter	Response
Maximum Average Current (average absolute value), mA	_____ @ 500 Ω
Maximum Average Power Density ^{††} , (W/cm ²), (using smallest electrode conductive surface area)	_____ @ 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 documentation. 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.

D. Device Safety

To be eligible for exemption from the 510(k) requirement, TENS devices with limited output for pain relief will have to conform to the following output limitations of proposed 21 CFR 882.5890(c)(1), if it is finalized:

The device utilizes a stimulus generator that delivers, into a resistive load, which represents the worse case of either 500 ohms or the typical load expected during normal conditions of use, the following:

- (i) a maximum charge per phase that does not exceed Q, where $Q = 20 + (28)(t)$ microcoulombs (and where t is the phase duration expressed in milliseconds and measured at 50 percent of the phase amplitude);
- (ii) a maximum average current that does not exceed 10 milliamperes (average absolute value);
- (iii) a maximum primary (depolarizing) phase duration that does not exceed 500 microseconds;
- (iv) an average DC current that does not exceed 100 microamperes when no pulses are being applied, or if the device fails;
- (v) a maximum current density that does not exceed 2 milliamperes r.m.s. per square centimeter of electrode conductive surface area; and
- (vi) a maximum average power density that does not exceed 0.25 watts per square centimeter of electrode conductive surface area.

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In order to assure device safety, you should follow these additional recommendations, which are applicable to TENS devices with limited output for pain relief. These recommendations supplement the safety information contained in the labeling section provided below.

- 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.
- Battery 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.
- The stimulus generator should be limited to use with a battery power source, should be isolated from earth ground, and should not be capable of use with an AC power source or use while connected to a battery charger.
- 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.*” This FDA-recognized standard recommends evaluation and testing of medical devices based upon the duration and type of contact. For cutaneous electrodes 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 maintain 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 device master records 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 TENS devices with limited output for pain relief are regulated as class II devices under 21 CFR 882.1320. FDA is also 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**

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Guidance Document: Cutaneous Electrode,⁴ when finalized, for specific recommendations on the types of information to document for this accessory.

Electrode Conductive Medium (Gel)

Electroconductive media used with TENS devices with limited output for pain relief are regulated as class II devices under 21 CFR 882.1275. FDA is also 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,**⁵ when finalized, for specific recommendations on the types of information to document for this accessory.

Electrode Lead Wires and Patient Cables

We recommend that you 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 documentation should contain information sufficient to demonstrate conformance to this mandatory performance standard.

Batteries

We recommend that you 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 you 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*” 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 TENS devices with limited output for pain relief controlled by software (or firmware or a microprocessor), we recommend that you document the appropriate information, based on the level of concern and recommendations described in the guidance document entitled, **Guidance**

⁴ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199247.htm>.

⁵ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199256.htm>.

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for the Content of Premarket Submissions for Software Contained in Medical Devices, (the Software guidance)⁶ in your design history file and device master records.

See the guidance for general information on this subject.

H. Electromagnetic Compatibility (EMC)

If performance characteristics related to EMC are described in your labeling, we recommend that you maintain, in your device master records, the valid scientific evidence that supports these performance characteristics.

6. Labeling

The following suggestions are intended to help you prepare labeling that satisfies the requirements of 21 CFR Part 801.⁷

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 that you prepare 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, a prescription 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 TENS devices with limited output for pain relief that are intended to be sold directly to lay users.

Device User Manual

We recommend that you provide a user manual with the device. In addition to the prescription statement above, the user manual should include descriptions of the following:

- the device and all accessories

⁶ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm>.

⁷ 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 are consistent with the requirements of 21 CFR Part 801.

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- 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.

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 TENS devices with limited output for pain relief. 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 TENS devices with limited output covered by this guidance document are those intended for pain relief. The intended use of devices of this type, including any indications for use, is limited to pain relief, including providing adjunctive therapy for pain management for medical purposes. Specific indications for use for the TENS device with limited output that we consider to be for pain relief include symptomatic relief of chronic intractable pain, relief of acute post-surgical and post-traumatic pain, and relief of pain associated with arthritis. The device should only be used under medical supervision for adjunctive therapy and should not be intended for use as a substitute for pain medications and other pain management therapies.

If a transcutaneous electrical nerve 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 transcutaneous electrical nerve stimulator is beyond the scope of this guidance document. Articles marketed for other intended uses may be subject to additional regulatory

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requirements, including premarket notification or premarket approval (sections 510(k) and 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 both the device master record and in the labeling, the particular indication for use that corresponds to each mode of operation.

Contraindications

We recommend that the user manual include the following statements:

- 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.
- Do not use this device on patients whose pain syndromes are undiagnosed.

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.

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Precautions

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

- TENS is not effective for pain of central origin, including headache;
- TENS is not a substitute for pain medications and other pain management therapies;
- TENS devices have no curative value;
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients;
- 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 (gel);
- 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

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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.

7. Limitations of Exemption from Premarket Notification

FDA's decision to exempt a class II device from the premarket notification requirement of the act is only to the extent that the device has existing and reasonably foreseeable characteristics of devices within that generic type that currently are, or have been, in commercial distribution. Section 21 CFR 882.9 specifies the limitations on exemption. If any of these limitations apply, your device is not exempt, and you must submit a premarket notification.