

§ 882.5894

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and electrical, mechanical, and thermal safety.

(3) The technical parameters of the device, including waveform outputs and temperature limits, must be identified.

(4) Cleaning validation of earpieces must be conducted.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include the following:

(i) Information on how the device operates and the typical sensations experienced during treatment;

(ii) A detailed summary of the device's technical parameters; and

(iii) Instructions for maintenance and cleaning of the device.

[83 FR 52973, Oct. 19, 2018]

§ 882.5894 Limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites.

(a) *Identification.* A limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites is a device intended to alleviate skin reactions associated with insect bites via cutaneous, piezoelectric stimulation at the local site of the bite.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Appropriate testing to characterize the electrical output specifications of the device (*i.e.*, total charge delivered, maximum instantaneous output current, maximum instantaneous output voltage, pulse duration, charge density) must be conducted.

(2) Mechanical bench testing must demonstrate that the device will withstand the labeled number duration of uses.

(3) All elements of the device that may contact the patient must be assessed to be biocompatible.

(4) Labeling must include:

(i) Validated instructions which addresses the following:

(A) Identification of areas of the body which are appropriate and not appropriate for contact with the device.

(B) Whether use of the device in conjunction with flammable materials (*e.g.*, insect repellent) is appropriate.

(C) Use of the device on or near implanted devices.

(D) How to identify the correct type of skin condition.

(ii) Technical parameters of the device (maximum output voltage (instantaneous), maximum output current (instantaneous), and pulse duration).

(iii) Language to direct end users to contact the device manufacturer and MedWatch if they experience any adverse events with this device.

(iv) The anticipated number of device uses prior to failure.

[80 FR 15165, Mar. 23, 2015]

§ 882.5895 Vibratory counter-stimulation device.

(a) *Identification.* A vibratory counter-stimulation device is a prescription device that provides electrically powered mechanical vibration to improve the quality of sleep in patients with primary Restless Legs Syndrome.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The special controls for this device are:

(1) Appropriate analysis/testing must demonstrate electromagnetic compatibility (EMC), electrical safety, and thermal safety.

(2) If the device contains software or firmware, appropriate verification, validation, and hazard analysis must be performed.

(3) The elements of the device that contact the patient must be assessed to be biocompatible.

(4) Non-clinical testing data (including vibration frequency, amplitude, and acceleration) must demonstrate that the device performs as intended under anticipated conditions of use.

(5) Labeling must include:

(i) Specific information pertinent to use of the device by the intended patient population and the treatment regimen;

(ii) Warning to only use the device on normal, intact, clean, healthy skin;

(iii) Warning to not use the device if the user has leg skin disorders, such as eczema, psoriasis, cellulitis, non-healing wounds;