

Regulatory Background of Nonthermal SWD Devices

21 CFR 890.5290 (b)

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Outline

- Definition
- Purpose of the Meeting
- Current Regulatory Pathway
- Cleared Indications
- Regulatory History
- Comments to the Docket

Regulatory Definition

21 CFR 890.5290 (a)

(a) *Shortwave diathermy for use in applying therapeutic **deep heat** for selected medical conditions-*

A shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the radio frequency bands of 13 MHz to 27.12 MHz and that is intended **to generate deep heat** within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. Class II

Regulatory Definition

21 CFR 890.5290 (b)

(b) Shortwave diathermy for all other uses-

A shortwave diathermy for all other uses except for the treatment of malignancies is a device that applies to the body electromagnetic energy in the radio frequency bands of 13 MHz to 27.12 MHz and that is intended for the treatment of medical conditions **by means other than the generation of deep heat** within body tissues as described in paragraph (a) of this section.

Class III  Hereinafter: “Nonthermal SWD”

Note: All cleared nonthermal SWD devices utilize a carrier frequency of 27.12 MHz.

Note: SWD devices intended for the treatment of malignancies would be considered postamendments Class III devices, requiring PMAs.

Purpose of This Meeting

- Nonthermal SWD devices are currently Class III, but marketed through the 510(k) process.
- FDA seeks the panel's input on the classification of nonthermal SWD devices.
- FDA will ask the panel to comment on whether:
 - Nonthermal SWD devices are life supporting, life sustaining, or of substantial importance in preventing impairment to human health.
 - Nonthermal SWD devices present an unreasonable risk of injury or illness.
 - Sufficient information exists to establish special controls to provide a reasonable assurance of safety and effectiveness.

Current Regulatory Pathway

- Class III, 510(k): Indications for use and technological characteristics are “substantially equivalent” as compared to a predicate(s)
- The earliest nonthermal SWD devices relied on comparison to “preamendments” devices (on the market prior to 1976)
- 11 total cleared devices

Cleared Indications for Use

- Adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue
- Treatment of edema following blepharoplasty
- Nonthermal SWD devices are cleared only for prescription use

Regulatory History

- Nonthermal SWD devices on the market prior to May 1976 are considered preamendments
- Classification meetings of 1975, 1976, 1977, and 1978 recommended a split classification
 - SWD devices “capable of generating therapeutic heat in specific areas of the body” → Class II
 - SWD devices for “any use other than delivering therapeutic deep heat” → Class III
 - Some SWD devices that used “pulsed radiofrequency outputs” could not provide a sufficient increase in tissue temperature and thus were considered therapeutically ineffective

1979 Proposed Rule

- The proposed rule recommended Class III
 - There is an unreasonable risk of injury without proven benefit to the patient for nonthermal SWD] **Class III**
 - Cannot establish an adequate performance standard because insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of nonthermal SWD
- Identified risks to health
 - Cellular or tissue injury
 - Pacemaker interference
 - Tissue necrosis (tissue death) and burns
 - Electrical shock

1979 Panel Meeting

- Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel
 - stated that to be therapeutically effective, a SWD device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44 °C

1983 Final Rule

- FDA agreed with the 1979 Panel
 - insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of nonthermal SWD
 - insufficient information existed to establish a performance standard to provide this assurance
- Classified SWD devices into split classification
 - **Class II** when intended for use in applying therapeutic deep heat for selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for malignancies
 - **Class III** for all other uses by means other than the generation of deep heat within body tissue except for the treatment of malignancies

2009 Notice

- Additional 515(i) for remaining class III preamendments devices published in 2009
 - Submissions were received from four nonthermal SWD manufacturers, and one submission from a manufacturer that does not yet have a marketed nonthermal SWD device
- FDA reviewed each submission

2012 Proposed Rule

- FDA published a proposed rule on July 6, 2012 to require premarket approval (Class III) for nonthermal SWD
 - Summary of proposed findings with respect to risks and benefits

<ol style="list-style-type: none"> 1. Cellular or tissue injury 2. Pacemaker interference 3. Tissue necrosis (tissue death) and burns 4. Electrical shock 	<ol style="list-style-type: none"> 1. Thermal Injury from Implanted Wire Leads and Metal Implants 2. Radiation Hazards 3. Abnormal Cell Growth
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1979

2012

- There is an unreasonable risk of injury without proven benefit to the patient for nonthermal SWD
- Cannot establish an adequate performance standard (special controls) because insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of nonthermal SWD

2012 Proposed Rule

- Public comment period
- FDA received five separate submissions, which were submitted to request a change in the classification of nonthermal SWD
- FDA reviewed the reclassification submissions and conducted a systematic literature review

Requested Indications for Use

- Submissions from Leroy Hamilton, Ph.D. and Regeneration Biomedical, Inc.
 - Per 21 CFR 890.5290(b): “medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.”
- Submissions from MEDlcept, Inc. and Diapulse Corporation of America
 - “Adjunctive use in palliative treatment of postoperative pain and edema in superficial soft tissue”

Requested Indications for Use

- Submission from BioElectronics Corporation
 - “Relief of menstrual pain and discomfort and relief of musculoskeletal pain”
 - Over the counter (OTC) designation

Note: FDA has not cleared nonthermal SWD devices for these indications or for OTC designation

Additional Proposed Risks to Health from Reclassification Submissions

1. Adverse pregnancy outcome
2. Cancer and tumor promotion
3. Skin reactions
4. Pain
5. Bleeding
6. Ineffective treatment
7. Risk to children
8. Feeling chilly and cold in response to treatment
9. Sensation of localized warmth
10. "Pins and needles" sensation
11. Gout attack in patients with pre-existing gout
12. Mild numbness in the area of treatment
13. Abdominal pain
14. Chest wall sensation
15. Headache
16. Malaise

Proposed Special Controls

- From responses to proposed rule of 2012:
 - Adequate instructions for use
 - Compliance with voluntary consensus standards
 - Non-clinical performance testing to provide a reasonable assurance of safety and effectiveness with respect to the output waveform and its specifications,
 - Submission of animal and clinical testing when a device uses a new waveform or technology that is not well-characterized

Comments to the Docket

- Over 240 comments received, with sources including:
 - Members of the patient, consumer, and public health coalition
 - Patients and their family members
 - Healthcare practitioners
 - Employees and shareholders of nonthermal SWD manufacturers
 - Nonthermal SWD distributors
- A few comments agreed with FDA's call for premarket approval, though most did not
- Anecdotal evidence of effectiveness for a range of conditions
- General lack of serious adverse events, though several were mentioned

Comments to the Docket

- Numerous indications for use cited such as:
 - Chronic pain
 - Ankle sprain
 - Wound healing
- Only the indications currently cleared are under discussion today
 - Adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue
 - Treatment of edema following blepharoplasty

Concluding Remarks

- FDA will present the available scientific evidence
- The Panel will be asked for their input on the classification of nonthermal SWD devices for the cleared indications for use
- Input from the Panel will be used to develop a proposed order regarding classification



Thank you!