



Food and Drug Administration
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January 15, 2015

Ecobrand, Ltd.
c/o Mr. Kevin Walls, RAC
Regulatory Consultant
Regulatory Insight, Inc.
5401 S. Cottonwood Court
Greenwood Village, CO 80121

Re: DEN100024
Zap-It!
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.5894
Regulation Name: Limited output transcutaneous piezoelectric stimulator for skin reactions
associated with insect bites
Regulatory Classification: Class II
Product Code: OSG
Dated: September 8, 2010
Received: September 9, 2010

Dear Mr. Walls:

This letter corrects our classification letter dated November 7, 2014.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Zap-It!, an over-the-counter device under 21 CFR Subpart C that is indicated for temporarily reducing the itching caused by mosquito bites. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Zap-It! and substantially equivalent devices of this generic type, into class II under the generic name, limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites.

FDA identifies this generic type of device as:

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

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1)

of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on August 13, 2010 automatically classifying the Zap-It! in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On September 9, 2010, FDA received your *de novo* requesting classification of the Zap-It! into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Zap-It! into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Zap- It! indicated for temporarily reducing the itching caused by mosquito bites can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Cutaneous burns	Characterization of Electrical Output Labeling
Adverse skin reactions	Biocompatibility Assessment
Damage to sensitive tissue (e.g., eyes, lips, inside mouth, open	Labeling
Infection	Labeling
Burns and other injuries due to ignition of flammable substances which may be used in the same intended use environment (e.g., insect	Labeling
Interference with implanted devices and other patient care devices	Labeling
Failure to identify correct population and condition	Labeling
Device failure	Non-clinical (Bench) Testing Labeling

In combination with the general controls of the FD&C Act, the limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites is subject to the following special controls:

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:
 - a. Validated instructions which addresses the following:
 - i. Identification of areas of the body which are appropriate and not appropriate for contact with the device;
 - ii. Whether use of the device in conjunction with flammable materials (e.g., insect repellent) is appropriate;
 - iii. Use of the device on or near implanted devices;
 - iv. How to identify the correct type of skin condition
 - b. Technical parameters of the device [maximum output voltage (instantaneous), maximum output current (instantaneous), and pulse duration].
 - c. Language to direct end-users to contact the device manufacturer and MedWatch if they experience any adverse events with this device.
 - d. The anticipated number of device uses prior to failure.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type need not submit a premarket notification containing information on the limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites they intend to market prior to marketing the device and receive clearance to market from FDA subject to the limitations on exemptions in 882.9.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305),

Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Michael Hoffmann at 301-796-6476.

Sincerely yours,

Jonette R. Foy -S

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