

**EVALUATION OF AUTOMATIC CLASS III DESIGNATION (DE NOVO) FOR
ZANZA-CLICK (OR DISC-O-CLICK, OR MINI-CLICK)**

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 882.5894

CLASSIFICATION: II (**Exempt** from premarket notification review, subject to the limitations in 21 CFR 882.9)

PRODUCT CODE: OSG

BACKGROUND

DEVICE NAME: Zanza-Click (or Disc-o-Click, or Mini-Click)

SUBMISSION NUMBER: DEN130019

DATE OF DE NOVO REQUEST: February 14, 2013

REQUESTOR CONTACT: Technimed S.r.l.
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REQUESTOR'S RECOMMENDED CLASSIFICATION: II

INDICATIONS FOR USE

Zanza-Click (or Disc-o-Click, or Mini-Click) is indicated for temporarily reducing the swelling and itching caused by mosquito bites.

Limitations

The Zanza-Click (or Disc-o-Click, or Mini-Click) device is available as an over-the-counter (OTC) device.

Please refer to the package insert for a complete list of Warnings and Precautions regarding the appropriate use of the Zanza-Click (or Disc-o-Click, or Mini-Click) device. The following statements are limitations of the device explicitly noted in the labeling:

Warnings

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device. Such use could cause electric shock, burns, or electrical interference.

Do not use the device in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when you are using the product.

Do not use over open wounds or rashes, or over infected or pathological or abnormal skin conditions, on bleeding or secreting areas, or if you are sensitive to electric stimulus. Do not use over viral lesions, as safety studies have not been performed to determine the effect of the device on viral lesions; therefore, the effects are unknown.

The safety and effectiveness has not been established in neonates, infants and children.

Do not use if you have used an insect repellent and/or flammable substances containing alcohol (for example: perfume, cologne, deodorant, etc.), as this device can ignite flammable substances. Wait until insect repellent and/or substances containing alcohol have thoroughly dried before using this device.

Cutaneous burns are a danger when applying repeated electrical stimulus to the skin in rapid succession, and the repeated excessive use of the device on bites has not been studied.

Do not use in or around sensitive areas such as the mouth, tongue, eyes, ear canal, internal part of the wrist or palms, mucous membranes etc.

Do not use with wet hands and on wet skin. If water seeps into the device, wait for it to completely dry off.

Use the device on a single patient.

The device cannot be sterilized. In case of accidental contact with open wounds or blood, do not use and dispose it after disinfection.

The device was only found in clinical studies to temporarily remove the itching and swelling. If you believe your mosquito bite is infected, seek medical attention.

Do not use the device to remove toxins or infection associated with mosquito bites.

Precautions

Discontinue use if irritation occurs.

If not used according to the Directions for Use, this product may cause sensitivity at the site of application.

Use caution if stimulation is applied over areas of skin that lack normal sensation.

Dry the area of the bite before apply the device, if necessary.

Keep out of the reach of children.

Zanza-Click (or Mini-Click, or Disc-o-Click) is a medical device. Do not use it as a toy! Do not let children play with Zanza-Click (or Mini-Click, or Disc-o-Click).

CONDITIONS OF EXEMPTION

Limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites are appropriate for exemption from premarket notification, subject to the limitations of exemptions identified in 21 CFR 882.9, because the applicable special controls and general controls provide reasonable assurance of safety and effectiveness, if device manufacturers follow the special controls requirements. Examples of exceeding the limitations of exemption are where the output (absolute charge delivered or current) exceeds the specifications for this device, the indications is for something other than itching and swelling, or the indications specify bites other than insect bites.

Exemption from the requirement of premarket notification for Limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites does not mean that these devices would be exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. FDA's proposal to exempt these devices from the requirement of premarket notification [510(k)] is based, in part, on the assurance of safety and effectiveness provided by other regulatory controls, such as current good manufacturing practice requirements (21 CFR part 820) and the identified special controls.

DEVICE DESCRIPTION

The Zanza-Click (or Disc-o-Click, or Mini-Click) is a hand held device, consisting primarily of housing, a push button (which the user depresses to excite the piezoelectric crystal by means of a spring), a "Piezo unit" (containing piezoelectric crystal) and electrical output terminals (placed flush to the user's skin) intended to deliver electrical current to the skin. Please refer to Figures 1-3 below for a graphical representation of the devices:



Figure 1. Zanza-Click



Figure 2. Disc-o-Click



Figure 3. Mini-Click

The user of the device places the end of the device containing the electrode output terminals (the end of the device opposite the push button) flush against the skin, at the site of the mosquito bite. The push button is manually depressed, which activates a spring to mechanically deform the piezoelectric crystal, and the electrical charge (high voltage, low amperage) travels via the electrode wires to the skin. Electrical charge may reach the skin via electrical conductive channel between the electrode terminals and skin, or electrical conductive channel through a small air gap to the skin (electrical spark). The deposition of the charge in the skin is intended to temporarily reduce the itch and swelling associated with the underlying mosquito bite.

The user may repeat activation of the device (a maximum of five activations per bite for children, and ten activations per bite for adults and adolescents) until the mosquito bite itch has been satisfactorily reduced; however, the user is also instructed that repeated use at the same site increases the risk of mild cutaneous burns.

The device is designed for external, limited duration intact skin contact for a single user in an environment free from fluids and is provided non-sterile.

The device contains no software.

The Zanza-Click (or Disc-o-Click, or Mini-Click) Device is for over-the-counter (OTC) use, as described in the package insert.

SUMMARY OF PERFORMANCE TESTING

Characterization of Electrical Output (Oscilloscope Tracings)

To characterize device electrical output, oscilloscope tracings of the output were provided, under loads of 500, 2,000, and 10,000 ohms to simulate the load presented by dry skin, while using a controlled and repeatable pressure to activate the piezoelectric element. The device output, as characterized by oscilloscope tracings measured with 10,000 ohm resistance, was 2.24 kV, and a current as high as 222.83mA.

Performance Testing, Mechanical Failure or Degradation

The device was tested to evaluate its ability to deliver at least 25,000 charges before it stops working. This testing showed that the device delivered at least 25,000 charges before it stops working.

The device is not provided sterile, which is acceptable for the Zanza-Click (or Disc-o-Click, or Mini-Click). The device is intended only for single patient use. It is intended only for external topical use and the labeling includes appropriate cleaning instructions for safe disposal of the device (in the event of inadvertent contact with an open wound/blood).

The sponsor stated a service life of 20,000 charges is to be expected based upon their testing and has identified such within the labeling.

Electromagnetic Compatibility and Electrical, Mechanical, and Thermal Safety

Electrical Safety testing was performed per IEC 60601-1:2006, and Electromagnetic Compatibility testing was performed per IEC 60601-1-2:2007.

Biocompatibility Analysis

The patient-contacting materials are a specific acrylonitrile butadiene styrene (ABS), styrene butadiene copolymer (SBC), and polypropylene. Justification was provided supporting biocompatibility of these materials for an externally-contacting, single user device.

Human Performance Testing

The effect of the device on mosquito bite itch and swelling (device benefit) was evaluated

Study Design

A prospective, double-blinded, placebo controlled clinical study which aimed to evaluate the safety (tolerance in the treated area and general tolerance) and the effectiveness (reduction/elimination of itching) of the Eco-Click device, manufactured by Tecnimed s.r.l., in healthy subjects aged 18-65 years was conducted. A total of 100 subjects were evaluated, half of which received the active device. The sham (control) device was designed to have the identical physical appearance and clicking sound as the active device. The sham device contained an active piezoelectric crystal, but the electric charge was diverted within the device instead of being delivered to the skin.

The effect of the blinding was examined after the study to assess whether patients could correctly identify the group (active or control) they were randomly assigned to.

Subjects were asked to rate their level of itch on a scale of 0 (no itching) to 10 (severe itching). The investigator measured the length, width, and height, in mm, the erythema of the mosquito bite using a caliper or a small ruler. The total size of the erythema was calculated as L x W x H.

Assessments were made for both itching and swelling at 10 min, 20 min, 40 min, 1 hour, 2 hours, 3 hours, 4 hours, 6 hours, and 24 hours post bite. Subjects were allowed to leave the test site after 1 hour. Assessments at 2, 3, 4, and 6 hours post bite are not performed at the test site. The subjects were provided with case report forms to fill out and bring back to the site at the 24 hour follow-up.

Results

Primary Endpoints

Outcome Measured	10 minutes (after first application)		1 hour (after first application)		
	Active Group	Control (Sham) Group	Active Group	Control (Sham) Group	Fisher's exact p-value (device treatment group-the sham group)
40% Itch reduction	56% (28 of 50)	34% (17 of 50)	98% (49 of 50)	94% (47 of 50)	p=0.62
10% Swelling reduction	50% (25 of 50)	28% (14 of 50)	86% (43 of 50)	48% (24 of 50)	p<0.0001

post hoc Analysis

Outcome Measured	1 hour (after first application)	
	Active Group	Control (Sham) Group
75% Itch reduction	96% (48 of 50)	80% (40 of 50)

Blinding Assessment

Ninety-six of the 100 subjects were assessed at the end of the study, 48 out of 50 from each group. It was found that of those assigned to the active group, 93.8% (45 of 48) correctly guessed that they were in the active group. In the control group, 79.2% (38 of 48) correctly guessed that they were in the control group.

Based on the similarities of skin between adults and adolescents, the data collected on adult population was extrapolated to justify the safe and effective use of the device on the adolescent population.

LABELING (PACKAGE INSERT)

To mitigate concerns regarding cutaneous burns, the following instruction is included in the labeling:

Apply 5 clicks first, as soon as possible after the mosquito has bitten. 10 minutes after the first application, if you still perceive itching, you may apply additional 5 to 10 clicks...However, do not apply more than 10 clicks at a time.

For children, the instructions state that only 5 additional clicks may be administered.

To mitigate concerns regarding mechanical failure (or degradation), the following statement is included in the labeling:

Works for up to 20,000 clicks!

To mitigate concerns regarding interference with implanted and patient care devices, the following warning is included in the labeling:

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device. Such use could cause electric shock, burns or electrical interference. Do not use the device in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when you are using the product.

To mitigate concerns regarding damage to sensitive tissues of the body, the following warnings are included in the labeling:

Do not use in or around sensitive areas such as the mouth, tongue, eyes, ear canal, internal part of the wrist or palms, mucous membranes etc.

Do not use over viral lesions, as safety studies have not been performed to determine the effect of the device on viral lesions; therefore, the effects are unknown.

Use caution if stimulation is applied over areas of skin that lack normal sensation.

To mitigate concerns regarding infection and damage to sensitive tissues, the following warnings are included in the labeling:

Do not use over open wounds or rashes, or over infected or pathological or abnormal skin conditions, on bleeding or secreting areas, or if you are sensitive to electric stimulus.

The device cannot be sterilized. In case of accidental contact with open wounds or blood, do not use and dispose it after disinfection.

Use the device on a single patient.

To mitigate concerns regarding ignition of flammable substances, the following warnings are included in the labeling:

Do not use if you have used an insect repellent and/or flammable substances containing alcohol (for example: perfume, cologne, deodorant, etc.), as this device can ignite flammable substances. Wait until insect repellent and/or substances containing alcohol have thoroughly dried before using this device.

To mitigate concerns regarding the lack of treatment of other medical conditions that are not intended to be treated with this device, the following warning is included in the labeling:

The device was only found in clinical studies to temporarily remove the itching and swelling. If you believe your mosquito bite is infected, seek medical attention.

Do not use the device to remove toxins or infection associated with mosquito bites.

To mitigate concerns regarding failure to report malfunctions or adverse events for this OTC device, the following instructions are included in the labeling:

*Please inform the manufacturer about eventual problems or malfunctions to reinforce the post-market surveillance. If you experience adverse events when using the device, please contact MedWatch at 1-800-332-1088 or the internet at:
<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>.*

Finally, the output parameters [maximum output voltage (instantaneous), maximum output current (instantaneous), and pulse duration] are included in the labeling:

*Maximum output voltage (instantaneous): 2.24 kV
Maximum output current (amperage): 222.83 mA
Duration of single discharge: 30 microseconds*

The Zanza-Click (or Disc-o-Click, or Mini-Click) device is available as an OTC device.

Labeling Comprehension Study

The Zanza-Click (or Disc-o-Click, or Mini-Click) device is intended for over-the-counter (OTC) use. Consequently, to ensure that the device could be used according to the proposed

labeling and instructions for use, the sponsor conducted a labeling comprehension study. The study included 100 subjects who were instructed to read the device labeling and subsequently complete a questionnaire. The questionnaire included 23 questions, each of which was intended to test the user’s interpretation of the cautionary language and instructions including the type of bite it is intended to treat and the certain conditions under which the device should not be used. The results indicated that patients understood the cautionary language and instructions for how to use the device.

RISKS TO HEALTH

Risks to health based on the technological characteristics of the Zanza-Click (or Disc-o-Click, or Mini-Click) were identified. Table 1 identifies the risks to health that may be associated with the use of limited output transcutaneous piezoelectric electrical stimulators for skin reactions associated with insect bites as well as the methods used to mitigate each risk.

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 wounds)	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 repellent)	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

SPECIAL CONTROLS

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.

BENEFIT/RISK DETERMINATION

The human performance study demonstrated a temporary reduction of itching and swelling following mosquito bites when this device was used. No adverse events were reported during the human performance study. Given the limited duration of the output and the small amount of charge delivered to the patient for one actuation, risks associated with the device are low.

Additionally, this device and devices similar to this device are on the market outside of the United States (OUS). A minimal number of adverse events have been reported and no regulatory actions have been taken in OUS jurisdictions in which this device is legally marketed, nor do any reports appear in the literature regarding adverse events for this type of device.

In conclusion, the data support that for the temporary reduction of itch and swelling associated with mosquito bites, the probable benefits outweigh the probable risks. These data also suggest that the individual patient's benefit from the device can be variable. In addition, the risks of the device can be mitigated by the use of general and special controls, including the labeling mitigations for the intended population.

CONCLUSION

The *de novo* request for the Zanza-Click (or Disc-o-Click, or Mini-Click) is granted and the device is classified under the following:

Product Code: OSG

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

Class: II (exempt from premarket notification, subject to the limitations in 21 CFR 882.9)

Regulation: 21 CFR 882.5894