DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Tecnimed S.r.l.
c/o Mr. Claude Berthoin
President
Thema USA
110 E. Granada Blvd., Suite 209
Ormond Beach, FL 32176

Re: DEN130019
Zanza-Click, Mini-Click, Disc-o-Click
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.5895
Regulation Name: Limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites
Regulatory Classification: Class II
Product Code: OSG
Dated: February 14, 2013
Received: February 28, 2013

Dear Mr. Berthoin:

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 Zanza-Click, Mini-Click, Disc-o-Click, an over-the-counter device under 21 CFR Subpart C that is indicated for temporarily reducing the itching and swelling caused by mosquito bites. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Zanza-Click, Mini-Click, Disc-o-Click 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.

On February 28, 2013, FDA received your *de novo* requesting classification of the Zanza-Click, Mini-Click, Disc-o-Click into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Zanza-Click, Mini-Click, Disc-o-Click 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 Zanza-Click, Mini-Click, Disc-o-Click indicated for temporarily reducing the itching and swelling 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 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 repellant)	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 Angela DeMarco at 301-796-4471.

Sincerely yours,

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K130488 / DEN130019 (GEN1300139)

Digital Signature Concurrence Table	
Reviewer Sign-Off	Angela DeMarco, 8/26/2014
Branch Chief Sign-Off	Michael Hoffmann August 27, 2014
Division Sign-Off	Carlos Pena October 31, 2014
Office Sign-Off	

Template Name: 1a – Order Granting the De Novo
Template History:

Date of Update	Updated By	Description of Update
10/26/2012	MMJ	Updated language to align with FDASIA. Placed in Digital Signature format.
11/27/2012	MMJ	Updated sig block to show Joni Foy's new title.
12/4/2012	MMJ	Updated Digital Signature table to add a block for Office-level signoff.
12/12/2012	MMJ	One digit was missing from 4-digit ZIP code extension in letterhead ("002" should read "0002"). Revised to fix this.
1/29/2014	MMJ	Revised to reflect OCC's recent feedback to OIR on recommended content for letters granting de novos, and to add some more minor edits provided by Joni Foy.
1/31/2014	MMJ	Added paragraph regarding compliance w/other requirements of the Act.
3/4/2014	MMJ	1st full paragraph on page 2, titled"[If Class II, choose this paragraph 2]:" Changed 1st sentence from "In addition to…" to "In combination with…"
3/17/2014	MMJ	Changed instructions on page 1 to "Exact name of CFR regulation - associated identification; do not list the regulation number"
4/11/2014	MMJ	Added correct acronyms for the FD&C Act