DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Pacer Therapeutics, Ltd.
% Ms. Susan P. D'Arcy
Unit 4 Horseshoe Park Pangbourne
Berkshire, United Kingdom
RGB 7JW

OCT 18 2012

Re: K083767
ViruLite Cold Sore Machine
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 878.4850
Regulation Name: Light based energy source device for topical application.
Regulatory Classification: Class II
Product Code: OKJ
Dated: June 25, 2009
Received: June 30, 2009

Dear Ms. D'Arcy:

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 ViruLite Cold Sore Machine, an over-the-counter Device under 21 CFR Part C that is indicated for shortening the time to healing of herpes simplex labialis lesions on or around the lips with time to healing defined as the time to patient described re-epithelialization. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the ViruLite Cold Sore Machine, and substantially equivalent devices of this generic type, into class II under the generic name, Light based energy source device used for topical application.

FDA identifies this generic type of device as:

> Light based energy source device for topical application. The device emits light energy at near infrared spectrum and is applied externally to the surface of herpes simplex labialis lesions on or around the lips.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by

means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act, also referred to as *de novo* classification or Evaluation of Automatic Class III Designation, 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).

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on June 10, 2009 automatically classifying the ViruLite Cold Sore Machine 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 June 25, 2009, FDA filed your *de novo* requesting classification of the ViruLite Cold Sore Machine into class II. The *de novo* request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ViruLite Cold Sore Machine 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 ViruLite Cold Sore Machine, indicated for shortening the time to healing of herpes simplex labialis lesions on or around the lips with time to healing defined as the time to patient described re-epithelialization, can be classified in class II with the establishment of special controls. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The potential risks and mitigations associated with the device type are summarized in Table 1.

Table 1 - Risks to Health and Mitigations

Identified Risks	Mitigation Measures
Redness and Discomfort	Clinical Performance Usability Study Labeling
Burns and Blisters	Clinical Performance Usability Study Labeling
Adverse Tissue Reaction	Biocompatibility

Infection/Transmissibility	Labeling Cleaning and Disinfection Validation Usability Study
Electrical Safety Issues	Electrical Safety Testing Labeling
Electromagnetic Incompatibility	Electromagnetic Compatibility Testing Labeling
User error	Usability Study Labeling
Ocular injury	Labeling Non-clinical Testing for Ocular Safety

In addition to the general controls of the FD&C Act, the Light based energy source device for topical application is subject to the following special controls: (1) The technical parameters of the device, including wavelength, treatment time, treatment area, energy density, spot size, and power are necessary to characterize and compare the device performance and must demonstrate a reasonable assurance of safety and effectiveness; (2) The cleaning and disinfection instructions for the device must be validated; (3) The device must be demonstrated to be biocompatible and non-toxic; (4) Appropriate testing must validate electromagnetic compatibility (EMC), ocular safety and electrical safety of the device; (5) Labeling must direct end-users to contact the device manufacturer and MedWatch in case they experience any adverse events when using this device; (6) Labeling must include specific information pertinent to use of the device by the intended patient population and the treatment regimen; (7) Simulated use testing must include information from a usability, label comprehension and self-selection study to demonstrate that the device can be used by the intended patient population without any assistance; and (8) Clinical data must show adequate reduction in time to healing and adequately address risks of redness, discomfort, burns, and blisters.

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 necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the light based energy source device for topical application they intend to market prior to marketing the device and receive clearance to market from FDA.

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*, 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 Mr. Mark N. Melkerson at (301) 796-5650

Sincerely,

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