December 28, 2017

Sanuwave, Inc.
% Glenn Stiegman
VP, Clinical and Regulatory Affairs
MCRA, LLC
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

Re: DEN160037
Trade/Device Name: dermaPACE System
Regulation Number: 21 CFR 878.4685
Regulation Name: Extracorporeal shock wave device for treatment of chronic wounds
Regulatory Class: Class II
Product Code: PZL
Dated: July 22, 2016
Received: July 25, 2016

Dear Glenn Stiegman:

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 dermaPACE System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The SANUWAVE dermaPACE System is indicated to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm^2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The dermaPACE System is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the dermaPACE System, and substantially equivalent devices of this generic type, into Class II under the generic name extracorporeal shock wave device for treatment of chronic wounds.

FDA identifies this generic type of device as:

> **Extracorporeal shock wave device for treatment of chronic wounds.** An extracorporeal shock wave device for treatment of chronic wounds is a prescription device that focuses acoustic shock waves onto the dermal tissue. The shock waves are generated inside the device and transferred to the body using an acoustic interface.

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 request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. 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 July 25, 2016, FDA received your De Novo requesting classification of the dermaPACE System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the dermaPACE System 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, for the previously stated indications for use, the dermaPACE System 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 the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk to Health	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation
Infection	Reprocessing validation Labeling
Inadequate healing	Labeling
Device failure / malfunction leading to application site injury	Non-clinical performance testing Electrical safety testing Electromagnetic compatibility (EMC) testing Use life testing Software verification, validation, and hazard analysis Labeling
Hearing loss	Non-clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the extracorporeal shock wave device for treatment of chronic wounds is subject to the following special controls:

1. Non-clinical performance testing must be conducted to demonstrate that the system produces anticipated and reproducible acoustic pressure shock waves.
2. The patient-contacting components of the device must be demonstrated to be biocompatible.

3. Performance data must demonstrate that the reusable components of the device can be reprocessed for subsequent use.
4. Performance data must be provided to demonstrate the electromagnetic compatibility and electrical safety of the device.
5. Software verification, validation and hazard analysis must be performed.
6. Performance data must support the use life of the system by demonstrating continued system functionality over the labeled use life.
7. Physician labeling must include:
    a. Information on how the device operates and the typical course of treatment.
    b. A detailed summary of the device's technical parameters.
    c. Validated methods and instructions for reprocessing of any reusable components.
    d. Instructions for preventing hearing loss by use of hearing protection.
8. Patient labeling must include:
    a. Relevant contraindications, warnings, precautions, adverse effects, and complications.
    b. Information on how the device operates and the typical course of treatment.
    c. The probable risks and benefits associated with the use of the device.
    d. Post-procedure care instructions.
    e. Alternative treatments.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

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 extracorporeal shock wave device for treatment of chronic wounds they intend to market prior to marketing the device.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Mehmet Kosoglu at 301-796-6194.

Sincerely,

Joshua Silverstein -S

For Angela C. Krueger
Deputy Director, Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health