November 15, 2017

Innovative Health Solutions, Inc. (IHS)
% Allison Scott, RAC
Navigant Consulting
9100 Keystone Crossing, Suite 500
Indianapolis, IN 46240

Re: DEN170018
Trade/Device Name: NSS-2 BRIDGE
Regulation Number: 21 CFR 882.5896
Regulation Name: Percutaneous nerve stimulator for substance use disorders
Regulatory Class: Class II
Product Code: PZR
Dated: March 16, 2017
Received: March 17, 2017

Dear Allison Scott:

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 NSS-2 BRIDGE, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The NSS-2 System is a percutaneous nerve field stimulator (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the NSS-2 BRIDGE, and substantially equivalent devices of this generic type, into Class II under the generic name percutaneous nerve stimulator for substance use disorders.

FDA identifies this generic type of device as:

> **Percutaneous nerve stimulator for substance use disorders.** A percutaneous nerve stimulator for substance use disorders is a device that stimulates nerves percutaneously to aid in the reduction of withdrawal symptoms associated with substance use disorders.

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 March 17, 2017, FDA received your De Novo requesting classification of the NSS-2 BRIDGE. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the NSS-2 BRIDGE 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 NSS-2 BRIDGE 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	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation Labeling
Electrical, mechanical, or thermal hazards leading to user discomfort or injury	Electromagnetic compatibility testing Electrical, mechanical, and thermal safety testing Non-clinical performance testing Software verification, validation and hazard analysis Labeling
Infection	Sterility testing Shelf life testing Labeling

In combination with the general controls of the FD&C Act, the percutaneous nerve stimulator for substance use disorders is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.

2. Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

3. Electrical performance testing of the device and electrodes must be conducted to validate the specified electrical output and duration of stimulation of the device.

4. Software verification, validation, and hazard analysis must be performed.

5. Sterility testing of the percutaneous components of the device must be performed.

6. Shelf life testing must be performed to demonstrate continued sterility, package integrity, and device functionality over the specified shelf life.

7. Labeling must include the following:
    a. A detailed summary of the device technical parameters;
    b. A warning stating that the device is only for use on clean, intact skin;
    c. Instructions for use, including placement of the device on the patient; and
    d. A shelf life.

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 percutaneous nerve stimulator for substance use disorders 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.

If you have any questions concerning the contents of the letter, please contact Eric Franca at 301-796-6285 or please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100, or at its internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Angela C. Krueger -S

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Deputy Director,
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Center for Devices and Radiological Health