August 9, 2019

Innovative Health Solutions (IHS), Inc.
% Allison Scott
Associate Director
Navigant
9100 Keystone Crossing, Suite 500
Indianapolis, Indiana 46240

Re: DEN180057
Trade/Device Name: IB-Stim
Regulation Number: 21 CFR 876.5340
Regulation Name: Non-implanted nerve stimulator for functional abdominal pain relief
Regulatory Class: Class II
Product Code: QHH
Dated: October 24, 2018
Received: October 25, 2018

Dear Allison Scott:

This letter corrects our classification order dated June 7, 2019.

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 IB-Stim, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The IB-Stim is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS). The IB-Stim is intended to be used for 120 hours per week up to 3 consecutive weeks, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination, as an aid in the reduction of pain when combined with other therapies for IBS.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the IB-Stim, and substantially equivalent devices of this generic type, into Class II under the generic name non-implanted nerve stimulator for functional abdominal pain relief.

FDA identifies this generic type of device as:

> **Non-implanted nerve stimulator for functional abdominal pain relief**. A non-implanted nerve stimulator for functional abdominal pain relief is a device that stimulates nerves remotely from the

source of pain with the intent to relieve functional abdominal pain. This generic type of device does not include devices designed to relieve pelvic pain.

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 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 announcing the classification.

On October 25, 2018, FDA received your De Novo requesting classification of the IB-Stim. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the IB-Stim 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 IB-Stim 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:

Identified Risks to Health	**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 non-implanted nerve stimulator for functional abdominal pain relief 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 labeled shelf life.

(7) Labeling must include the following:
   (i) A detailed summary of the device technical parameters;
   (ii) A warning stating that the device is only for use on clean, intact skin;
   (iii) Instructions for use, including placement of the device on the patient; and
   (iv) A shelf life.

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

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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 non-implanted nerve stimulator for functional abdominal pain relief 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 Eric Franca at 301-796-6285.

Sincerely,

Carlos L. Pena -S

Carlos Pena, PhD, MS
Director
OHT5: Office of Neurological
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