September 14, 2023

Transtimulation Research, Inc.
% Eric Bannon
Regulatory Consultant
AlvaMed, Inc
935 Great Plain Ave.
Suite 166
Needham, Massachusetts 02492

Re: K230526
Trade/Device Name: TEA Device
Regulation Number: 21 CFR 876.5340
Regulation Name: Nonimplanted Nerve Stimulator For Functional Abdominal Pain Relief
Regulatory Class: Class II
Product Code: QHH
Dated: August 17, 2023
Received: August 18, 2023

Dear Eric Bannon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
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General Hospital and Urology Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230526

Device Name
Transcutaneous Electrical Applicator (TEA), Model: SNM-FDC01

Indications for Use *(Describe)*

The Transcutaneous Electrical Applicator (TEA) is a transcutaneous electrical nerve field stimulator system intended to be used in adult patients with functional abdominal pain associated with irritable bowel syndrome (IBS) through application to Cranial Nerves V, VII, IX and X, and the occipital nerves, as an aid in the reduction of pain when combined with other therapies for IBS. TEA device is intended to be used for 7-120 hours per week up to 3 consecutive weeks.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1 510(K) SUMMARY (K230526)

1.1 Name and Address of Submitter

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1.3 Submission Information

Date Summary Prepared:	September 9, 2023
Device Name:	Transcutaneous Electrical Applicator (TEA), Model: SNM-FDC01
Common Name:	TEA Device
Code, Regulation Number:	QHH, 21 CFR 876.5340
Regulation Description:	Nonimplanted nerve stimulator for functional abdominal pain relief
Device Classification:	Class II
Review Panel:	Neurology

1.4 Predicate and Reference Device

The predicate and reference device are listed below:

	Predicate Device	**Reference Device**
510(k) Number	DEN180057	K212377
Device Name	IB-Stim	Transcutaneous Electrical Applicator (TEA), Model: SNM-FDC01
Submitter Name	Innovative Health Solutions, Inc.	Ningbo MedKinetic Medical Device Co., Ltd.
Regulation	21 CFR 876.5340 - Nonimplanted nerve stimulator for functional abdominal pain relief	21 CFR 882.5890 - Transcutaneous electrical nerve stimulator for pain relief
Classification	Class II	Class II
Code	QHH	NUH, NYN

1.5 Device Description

The TEA Device is a non-invasive, battery-operated, prescription-based transcutaneous electrical nerve field stimulator indicated for use in adult patients with functional abdominal pain associated with the irritable bowel syndrome (IBS).

The system includes the following components: TEA Device, lead cable, USB charging cable, USB power adapter, electrode pads, holding clip, and TEA IBS app. The device can be used in clinical environments (i.e., outpatient clinics and hospitals) and/or at home.

The TEA Device is powered by an internal rechargeable lithium polymer battery and uses a microprocessor to control the working modes, the waveform and strength of the output pulse. The electric pulse generator is based on a current source circuit. The power management module contains a DC-DC boost conversion circuit that provides the required voltage for the electric pulse generator. The TEA Device is able to connect with the TEA IBS app, which is located on a smartphone. The user interface is available on both the TEA Device and TEA IBS app. The user can power on/off the device, adjust treatment time and treatment intensity. Treatment time is adjustable within the of range 5~240 minutes per treatment session with a maximal operating time of 8.6 hours per day. In addition, there is over-load, over-current and no-load protection as well as an automatic shut-off function. The Bluetooth transceiver module is responsible for communication between the TEA Device and TEA IBS app located on a smartphone.

1.6 Summary of Substantial Equivalence Comparison to the Predicate Device

The subject device has the same intended use and similar technological characteristics as the predicate device. A minor population difference in the indication (modification in the patient population from pediatric to adult) does not alter the intended use and does not affect the device's safety and efficacy. The reference device was selected to support scientific methodology or standard reference values. The comparison of the subject device with the predicate and reference devices is shown in Table 1.

TRI Transtimulation Research Inc	Traditional 510(k): TEA Device	Page: 1-4

Table 1: Comparison of Subject Device with Predicate and Reference Devices

	Subject Device	**Predicate Device**	**Reference Device**
K Number	TBD	DEN180057	K212377
Manufacturer	Ningbo MedKinetic Medical Device Co., Ltd.	Innovative Health Solutions, Inc.	Ningbo MedKinetic Medical Device Co., Ltd.
Device Trade Name	Transcutaneous Electrical Applicator (TEA), Model SNM-FDC01	IB-Stim	Transcutaneous Electrical Applicator (TEA), Model SNM-FDC01
Common Name	TEA Device	IB-Stim	TEA Device
Regulation Number	21 CFR 876.5340	21 CFR 876.5340	21 CFR 882.5890
Regulation Description	Non-Implanted Nerve Stimulator for Pain Associated with Irritable Bowel Syndrome (IBS)	Non-Implanted Nerve Stimulator for Pain Associated with Irritable Bowel Syndrome (IBS)	Transcutaneous electrical nerve stimulator for pain relief
Device Classification	Class II	Class II	Class II
Product Code	QHH	QHH	NUH, NYN
Device Panel	Neurology	Neurology	Neurology
Indications for Use	The Transcutaneous Electrical Applicator (TEA) is a transcutaneous electrical nerve field stimulator system intended to be used in adult patients with functional abdominal pain associated with irritable bowel syndrome (IBS) through application to Cranial Nerves V, VII, IX and X, and the occipital nerves, as an aid in the reduction of pain when combined with other therapies for IBS. TEA device is intended to be used for 7-120 hours per week up to 3 consecutive weeks.	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 the 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, VI, 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.	Transcutaneous Electrical Applicator (TEA) is an Over-The-Counter device to be used by adults only for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, arm, and leg, due to strain from exercise or normal household work activities and suitable for home use.
Location of Use	Cranial Nerves V, VII, IX and X, and the occipital nerves	Cranial Nerves V, VII, IX and X, and the occipital nerves	Sore and aching muscles in the shoulder, waist, back, neck, arm, and leg
Patient Population	Adult	Child	Adult

1.7 Performance Testing Summary

The TEA Device and its components were tested to validate the safety and effectiveness of the device. The TEA Device has equivalent performance specifications when compared to the predicate device. The Model SNM-FDC01 has been previously cleared under K212377 with the identical design and performance specification. In addition, that the electrode pad has been previously cleared under K182111 with the identical design and performance specification

The following performance data were provided in support of the substantial equivalence:

Biocompatibility Testing

The biocompatibility evaluation for the TEA Device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

Cytotoxicity
Irritation

The TEA pads and Device were evaluated for skin contact for prolonged use (>24 hours to 30 days)

Electrical safety, electromagnetic compatibility, wireless testing

Electrical safety and EMC testing were conducted on the TEA Device. The system complies with the IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC. Battery evaluation was conducted to IEC 62133-2.

In addition, compliance was demonstrated to FCC 47 CFR Part 15 Subpart C, ANSI IEEE C63.27 for radio and wireless testing.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern,

Shelf Life

The shelf life of the TEA electrode pad was demonstrated to be 2 years.

1.8 Clinical Studies

Data from a randomized sham-controlled clinical study is submitted to support the safety and efficacy of the TEA Device.

A total of 42 patients (32 female and 10 male) with IBS-C were recruited and randomly allocated to: 1) 4-week TEA therapy group or 2) 4-week sham-TEA therapy group. 21 patients were recruited, with 2 patients in the sham-TEA therapy group dropping out during the study, so only 19 patients completed the study in the sham-TEA therapy group. Constipation was evaluated using the complete spontaneous bowel movements (CSBMs) per week and Bristol stool form scale (BSFS), while the abdominal pain was measured using the visual analog scale (VAS).

Evaluations of constipation and abdominal pain were performed at baseline and after the 4-week therapy with either therapy performed daily for 1 hour (30 minutes in the morning and 30 minutes in the evening), with two TEA electrode pads applied bilaterally at the auricular cymba concha (one electrode on each cymba concha) and two TEA electrode pads applied bilaterally at the sham location of elbow area (one electrode on each elbow).

After the 4-week period, the number of CSBMs/week in the TEA group tripled in comparison with the sham-TEA group (2.8 ± 2.2 vs. 0.9 ± 0.9, $P < 0.01$), the BSFS score in the TEA group doubled in comparison with the sham-TEA group (3.7±1.3 vs. 1.8 ± 1.1, $P < 0.001$), and the VAS score in the TEA group was about one third of that in the sham-TEA group (3.1 ± 2.2 versus 1.1 ± 1.1, $P < 0.01$). No adverse effects were observed in the TEA group.

Based on these results, the study concluded that the 4-week daily TEA therapy produced considerable benefits to patients in relieving the symptoms of constipation and abdominal pain without introducing any significant risks. In summary, the TEA therapy was shown to be safe and effective treatment of constipation and abdominal pain in IBS.

1.9 Special controls

Per regulation 21 CFR 876.5340 the special controls for this device are as follows:

- The patient-contacting components of the device must be demonstrated to be biocompatible.
- Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.
- Electrical performance testing of the device and electrodes must be conducted to validate the specified electrical output and duration of stimulation of the device.
- Software verification, validation, and hazard analysis must be performed.
- Sterility testing of the percutaneous components of the device must be performed.
- Shelf-life testing of the electrode pad must be performed to demonstrate continued package integrity and device functionality over the labeled shelf life.
- Labeling must include the following:

  (i) detailed summary of the technical parameters;

(ii) warning stating that the device is only for use on clean, intact skin;

(iii) instructions for use, including the electrode placement on the patient; and

(iv) shelf life (for the electrode pad)

1.10 Conclusion

The subject device has the same principle of operation and similar technological characteristics as the predicate. A minor population difference in the indication (modification in the patient population from pediatric to adult) does not alter the intended use and does not affect the device's safety and efficacy. Any differences identified in the technological characteristics do not raise any issues of safety or effectiveness.

The subject device has the required performance data, including bench, biocompatibility, and clinical data, indicating compliance with standards.

We therefore consider the Transcutaneous Electrical Applicator (TEA) to be substantially equivalent to the predicate and reference device listed above. The information presented in this 510(k) supports the subject device as safe, effective, and performs as well as the predicate device.