April 3, 2023

Avation Medical, Inc.
Manish Vaishya
Chief Technical Officer
1375 Perry Street
Columbus, OH 43201

Re: K220454
Trade/Device Name: Vivally System Wearable, Non-Invasive Neuromodulation System and Mobile Application
Regulation Number: 21 CFR§ 876.5310
Regulation Name: Nonimplanted, peripheral electrical continence device
Regulatory Class: II
Product Code: NAM
Dated: March 2, 2023
Received: March 3, 2023

Dear Manish Vaishya:

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,

Angel A. Soler-garcia -S

for
Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K220454

Device Name
Vivally System Wearable, Non-Invasive Neuromodulation System and Mobile Application

Indications for Use *(Describe)*

The Vivally® System is a wearable neuromodulation system to treat patients with the bladder conditions of urge urinary incontinence and urinary urgency.

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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AVATION MEDICAL

510 (k) Summary

1. Submitter Information

510 (k) submitter	Avation Medical, Inc.
Address	1375 Perry St, Suite 13-150 Columbus, OH 43201
Contact Person	Manish Vaishya, PhD Chief Technology Officer Phone: 614.591.4201 Email : Manish@Avation.com
Preparation date	March 31, 2023

2. Device Name

Trade Name of the Device	Vivally System Wearable, Non-Invasive Neuromodulation System and Mobile Application
Common Name	Non-implanted peripheral nerve stimulator for incontinence
Classification Name	Nonimplanted, Peripheral Electrical Continence Device
Classification Regulation	21 CFR 876.5310
Device Class	II
Panel	Gastroenterology/Urology
Product Code	NAM

3. Predicate and Reference Devices

	Predicate	Reference
510(k) Number	K192731	K132561
Trade Name of the Device	ZIDA Wearable Neuromodulation System	NURO Neuromodulation System

4. Device Description

The Vivally System is a wearable, non-invasive, bladder control therapy with a mobile application to treat patients with the conditions of urge urinary incontinence and urinary urgency, without the need for surgery, implants, drugs, or needle-electrodes.

The Vivally System utilizes neuromodulation to deliver electrical signals to the tibial nerve. The tibial nerve is a mixed (motor and sensory) peripheral nerve that feeds into the sacral plexus which contains the nerves that innervate the detrusor muscle surrounding the urinary bladder. The Vivally System also includes an analog input that measures the electromyogram (EMG) signal from the patient's foot via three additional EMG electrodes embedded on the Garment. The system operates in a combination of closed-loop using EMG as the physiological feedback, as well as in open-loop when the feedback signal is unreliable or unreadable.

The main components of the Vivally System include a rechargeable-controller (Stimulator) powered by a rechargeable lithium-ion battery, an ankle worn Garment designed to be used on the left or right ankle, Gel Cushions and charging accessories.

The Vivally System also includes a mobile application on the patient's personal device and a HIPAA-compliant cloud database. The Vivally Mobile Application allows the patient to start and manage a therapy session and provides access to condition support tools such as an electronic bladder diary to record symptoms, fluid intake and other factors impacting their condition and a record of therapy compliance. The HIPAA-compliant Vivally Cloud Database collects patient therapy statistics, therapy compliance and symptom tracking over time and can be accessed by the patient and physician as a tool to monitor and manage treatment.

5. Indications For Use

The Vivally® System is a wearable neuromodulation system to treat patients with the bladder conditions of urge urinary incontinence and urinary urgency.

6. Comparison of the Technological Characteristics with primary Predicate and Reference Devices

Device & Predicate Device(s):	K220454	K192731 (Predicate)	K132561(Reference)
Device Name	Vivally	ZIDA Wearable Neuromodulation System	Nuro Neuromodulation System
Indications for Use	The Vivally® System is a wearable neuromodulation system to treat patients with the bladder conditions of urge urinary incontinence and urinary urgency.	ZIDA Wearable Neuromodulation System is a neuromodulation system that is intended to treat patients with an overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence	The Nuro neuromodulation system (stimulator model Nuro 100) is intended to treat patients with overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.
Prescription or OTC	Prescription	Prescription	Prescription
Operating Principle	It is a non-invasive wearable bladder control therapy system utilizing neuromodulation to treat patients with bladder conditions of the urge urinary incontinence and urinary urgency by stimulating the tibial nerve.	It is a non-invasive wearable device which provides transcutaneous electrical stimulation of the posterior tibial nerve to treat OAB.	It is designed as a percutaneous tibial nerve stimulation system (PTNS) to deliver retrograde access to the sacral nerve plexus through percutaneous electrical stimulation of the posterior tibial nerve treat overactive bladder (OAB) and associated symptoms.
	For closed loop operation EMG electrodes are embedded on the Garment	No EMG electrodes are present	No EMG electrodes are present
Power source	Rechargeable Battery	1x AAA Battery (non-rechargeable)	Rechargeable Battery

	240-mAh, 3.7V Li-Ion		130-mAh, 3.7V Li-Ion
Number of Output Modes	4 modes: Calibration, therapy, test therapy, and diary	2 modes: Therapy and testing	2 modes: Calibration and Therapy
Therapy schedule	30 minutes per session, 1x or 3x per week or as prescribed by clinician	30 minutes per session, 1x per week	1x per week
Therapy session duration	30 minutes	30 minutes	30 minutes
Wireless Technology	Bluetooth	Not present	Not present
Electrode dimension (each)	22 X 50 mm Estimated surface area of 996 mm^2	20 X 40 mm Estimated surface area of 800 mm^2	34 gauge Acupuncture needle electrode
Stimulation Frequency	20 Hz	20 Hz	20 Hz
Pulse width	40 – 600 us	200 µs, fixed	200 us
Current amplitude	20 mA fixed	0-156 mA, adjustable	0 – 9 mA pk-to-pk
Electrode material	Silver ink coating	80% nylon 20% silver	Needle: stainless steel

As evidenced by the above table, both the subject and the predicate devices have similar intended use, but the subject and predicate devices have different technological characteristics. However, performance testing was conducted on the subject device, and it was established that the differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

7. Non-Clinical Testing

Below is a list of the tests that have been performed and successfully completed for the subject device per the below guidance and standards:

- Biocompatibility testing according to ISO 10993-1:2018 - *Biological evaluation of medical devices* — Part 1: Evaluation and testing within a risk management process and FDA Guidance "*Use of International Standard ISO 10993-1*" (2016).

- Electrical Safety testing according to IEC 60601-1: 2020 - *Medical electrical equipment – Basic safety and essential performance*

- Electromagnetic Compatibility testing according to IEC 60601-1-2: 2020 - *General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests*

- IEC 60601-2-10:2016 – *Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*

- IEC 60601-1-10 Ed 1.2 :2020 - *General Requirements for Basic Safety And Essential Performance - Collateral Standard: Requirements For The Development Of Physiologic Closed-Loop Controllers*

- IEC 62366-1 Ed 1.1: 2020 - *Medical devices - Part 1:Application of Usability Engineering to Medical Devices*

- Software Verification and Validation Testing according to FDA's Guidance "*Guidance for*

the Content of Premarket Submissions for Software Contained in Medical Devices"

Additionally, performance bench data was submitted for device performance and durability of the subject device. This data included:

- o Stimulation performance and closed-loop functionality tests.
- o Testing for Medical Devices Home Use, including environmental, operating, shock and vibration.
- o System and component durability and cycle testing.
- o Use case testing for comfort, safety and tolerability.
- o Cybersecurity testing

All predetermined acceptance criteria were met.

8. Clinical Study Summary

To confirm the safety, effectiveness of the subject device, Avation Medical conducted a prospective, multi-center study which evaluated the safety and effectiveness of the Vivally System for thirty minutes per session one to three times per week for 12 weeks , and then once every other week in the long-term follow up. After 12 weeks, subjects who met additional inclusion/exclusion criteria, such as completion of the 12 weeks of study with a minimum compliance of 90% for diary entries were able to continue in the long-term follow-up (24 months) portion of the study to assess the sustainability of therapeutic effect provided by the subject device. However, only 12 month follow-up data were submitted to support this 510(k).

Nine centers within the United States screened and enrolled subjects that met the inclusion and exclusion criteria. 96 subjects, confirmed to suffer from one or more symptoms of OAB as measured by a baseline 3-day bladder diary, and who met the other inclusion and exclusion criteria, were enrolled into the study. 88.5% subjects in the study were female. 80.2% study subjects were white and 10.4% were black. Mean age of the subjects was 60.8 years. Objective confirmation of the activation of the subject's tibial nerve (via EMG signal feedback) was achieved, and a personalized therapeutic range was set for each subject by their physician. Therapy sessions were performed by the subject at-home for 30 minutes per session, one to three times per week for 12 weeks, and twice per month during the long-term follow up portion. 96 subjects were enrolled and included in the Intent-to-Treat (ITT) population, 94 were deemed evaluable and 73 were deemed per protocol (PP). 47 subjects continued in the long-term follow-up phase of the study and completed the 6 month follow-up, followed by 39 for 12 months follow-up.

<u>Baseline Symptoms – Daily average events per day:</u>

OAB Symptom	ITT (N=96)		PP (N=73)	
	Number of Subjects Reporting Symptom (%)	Average Daily of Symptom Events at Baseline (Mean ± SD; Median [Min, Max])	Number of Subjects Reporting Symptom (%)	Average Daily Symptom Events at Baseline (Mean ± SD; Median [Min, Max])
UUI (Urinary Incontinence events)	76 (79.1%)	4.82 ± 4.13 3.67 [0.33, 16.0]	58 (79.5%)	4.92 ± 4.13 3.83 [0.33, 15.67]
Urges (Urinary urgency events)	74 (77.1%)	6.94 ± 5.85 6.0 [0.33, 28.0]	54 (74.0%)	6.99 ± 6.06 6.67 [0.33, 28.0]
Voids (Voiding frequency)	89 (92.7%)	13.34 ± 4.13 12.0 [8.67, 38.33]	73 (100%)	13.28 ± 3.13 12.0 [10.0, 28.0]

Effectiveness Outcome:

Effectiveness results were measured using responder rate, where a responder is a subject with an improvement of 50% or greater over baseline symptoms for UUI and urinary urgency events, and 30% improvement over baseline for voiding events. The responder rates at 12 weeks, 6 months and 12 months are listed in the table below-

Responder Rates and Daily Average Symptom Event Reduction

Treatment duration	Effectiveness Metric	UUI (Incontinence Events, ≥ 50% improvement)	Urges (Urgency Events, ≥ 50% improvement)	Voiding Frequency (Voiding Events, ≥ 30% improvement)
12 Weeks (N = 94)	# with symptoms at baseline (Y)	76	74	89
	# of responders (X)	47	41	31
	Responder Rate (X/Y)*100%	61.8%	55.4 %	34.8 %
	Symptom Event Reduction (Mean ± SD; Median [Min, Max])	1.91 ± 3.10 1.33 [-8.67, 11.67]	3.10 ± 3.85 2.33 [-3.0, 23.0]	2.92 ± 2.53 3.0 [-3.67, 10.33]
6 months (N = 47)	# with symptoms at baseline (Y)	43	36	44
	# of responders (X)	27	25	15
	Responder Rate (X/Y)*100%	62.8 %	69.4 %	34.1 %
	Symptom Event Reduction (Mean ± SD; Median [Min, Max])	2.13 ± 3.03 1.67 [-9.0, 10.0]	3.97 ± 5.22 2.17 [-4.0, 23.0]	2.67 ± 2.50 2.50 [-4.67, 7.0]
12 months (N = 39)	# with symptoms at baseline (Y)	35	29	36
	# of responders (X)	22	20	10
	Responder Rate (X/Y)*100%	62.9 %	69.0 %	27.8 %
	Symptom Event Reduction (Mean ± SD; Median [Min, Max])	1.29 ± 3.85 1.67 [-10.67, 10.33]	2.84 ± 4.87 1.33 [-5.0, 21.0]	1.85 ± 2.80 2.33 [-6.33, 5.33]

Safety Outcome:

The sponsor reported a total of 77 adverse events throughout the first 12 weeks of the study among which 61 were mild. The sponsor reported 12 device/procedure related adverse events which were all mild or moderate. No device-or procedure related severe adverse events were reported. The device or procedure related adverse events were foot pain (02), foot cramp (02), foot contusion (01), frequent urination (03), skin irritation (01), mild thermal burn (01) and urinary incontinence (01). One subject exited the study due to frequent urination. All the other adverse events were resolved either by reducing the stimulation parameters or replacing the device components (e.g., gel cushion replacement resolved the adverse event related to mild thermal burn).

In the long-term follow up to 12 months, 12 additional adverse events were recorded, all listed as mild (10) to moderate (2) and only one noted as possibly related to the device. That adverse event was recorded as prominent varicose veins. No treatment was needed for the adverse event.

Quality of Life (QOL):

5 QOL (OAB-q, I-QoL, IIQ-7, PGIC, and OHG) assessments were conducted as part of the clinical study. Outcomes for all QOL domains exceeded the threshold validated for the minimal clinically important difference confirming that the Vivally System has a positive impact on Quality of Life.

Assessment of Clinical Data:

The statistical analysis of the clinical data was not pre-specified and post-hoc in nature. Therefore, all the clinical data presented in this summary are descriptive.

The clinical data submitted in this 510(k) demonstrate the subject device provides a clinically meaningful improvement in UUI and urinary urgency symptoms. While the lack of pre-specified statistical analyses increases the uncertainty around the clinical data, considering the favorable safety profile of the device, the non-invasive nature of the treatment, the potential for the device to increase accessibility of the treatment, and the percent of responders for UUI and urinary urgency, the benefits of the device in treating the specific symptoms of UUI and urinary urgency outweigh the risks.

9. Conclusions

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.