March 19, 2021

Exodus Innovations
℅ Cherita James
Regulatory Consultant
M Squared Associates, Inc.
575 8th Avenue, Suite 1212
New York, NY 10018

Re: K192731
Trade/Device Name: ZIDA Wearable Neuromodulation System
Regulation Number: 21 CFR§ 876.5310
Regulation Name: Nonimplanted, Peripheral Electrical Continence Device
Regulatory Class: II
Product Code: NAM
Dated: February 26, 2021
Received: March 1, 2021

Dear Cherita James:

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,

Jessica 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192731

Device Name
ZIDA Wearable Neuromodulation System

Indications for Use *(Describe)*
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.

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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510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for ZIDA 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: Exodus
1 Exodus Road
Sufa, 85457
Israel
Isaac Oppenheim
Israel Office: 08-611-5525
US: 703-466-0259

Contact: Cherita James
M Squared Associates, Inc.
127 West 30th St, 9th Floor
New York, NY 10001
Ph: 347-954-0624
Fax: 703-562-9797
Email: Cjames@MSquaredAssociates.com

Date of Submission: March 18, 2021

Proprietary Name: **ZIDA Wearable Neuromodulation System**

Common Name: non-implanted peripheral nerve stimulator for incontinence

Regulatory Class: II

Regulation: 876.5310 Nonimplanted, peripheral electrical continence device.

Product Codes: NAM

Predicate Device: Urgent PC Neuromodulation System, K071822, NAM

Device Description: ZIDA Wearable Neuromodulation System (ZIDA System) is a home-use system that is a neuromodulation system designed to deliver non-invasive access to the sacral nerve plexus through transcutaneous electrical stimulation of the posterior tibial nerve. The method of treatment is referred to as Transcutaneous Tibial Nerve Stimulation (TTNS).
The ZIDA System is a combination of the battery powered ZIDA Control Unit and the ZIDA Embedded Garment (Sock or Tights).

Indications for Use: 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.

Substantial Equivalence Rationale

The claim of substantial equivalence of the ZIDA Wearable Neuromodulation System (ZIDA System) to the product identified above is based on the comparison of the indications for use, intended use, principles of operation, mechanism of action, and performance characteristics.

Indications and Intended Use

Both the ZIDA System and the Urgent PC have similar intended use: to treat patients with Overactive Bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence by weekly 30- minute stimulation of the nerve fiber at the posterior tibial nerve.

	ZIDA System **Subject device**	**URGENT PC UPC 200-A**
K#	TBD	K071822
Product Code	NAM	NAM
Indication for Use	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 Urgent PC Neuromodulation System is intended to treat patients with an overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.
Target population	OAB patients/male and female	OAB patients/male and female
Intended use	Nerve stimulation through transcutaneous electrical stimulation of the posterior tibial nerve (TTNS) near the ankle	Nerve stimulation through percutaneous electrical stimulation of the posterior tibial nerve (PTNS) near the ankle
Intended user	Prescription device for home use	Prescription device for physician use in office
Treatment duration	Twelve 30 minute tx once per week. If symptoms reappear, revert to last previously effective tx schedule	Twelve 30 minute tx once per week. If symptoms reappear, revert to last previously effective tx schedule

Control Unit Characteristics

The Control Unit differences between the subject and predicate device are minimal.

Description	ZIDA	URGENT PC UPC 200-A
K#	TBD	K071822
Power Source(s)	1 x AAA battery	9V battery
Number of Output Modes	2 Test Mode Therapy mode	2 Test Mode Therapy mode
Timer Range (minutes)	Yes, treatment shuts down after 30 minutes countdown	Yes, treatment mode shuts down after 30 minutes countdown
Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2 IEC 60601-2-10,
Compliance with 21 CFR 898?	N/A- no lead wires, control unit snaps to garment electrode	Unknown
Weight (g)	26g	unknown
Dimensions (mm) (W x H x D)	65mm X 40mm X 17mm	150mm X 75mm X 50mm
Housing Materials and Construction	ABS/PC	ABS/PC

Device Outputs

While the maximum outputs of the ZIDA Control Unit are greater than those of the Urgent PC, they are within the normal outputs of the TENS devices commonly prescribed for pain. As the mechanism of action is Posterior Tibial Nerve Stimulation, and the subject device utilizes skin contacting electrodes, the required output is higher than for the predicate device that has a percutaneous needle electrode. The outputs of the ZIDA Control Unit does not present new issues of safety or effectiveness.

Description	**ZIDA**	**URGENT PC UPC 200-A**	**Substantial Equivalence**
K#	TBD	K071822	--
Waveform	Monophasic square wave	Monophasic square wave	Same waveform
Shape	rectangular	rectangular	Same shape
Current	Adjustable from 0-156 mA (9.9mA RMS)	Adjustable from 0-19mA	The method of delivery of the ZIDA is a skin contact garment electrode, while the Urgent PC is a needle electrode. Differences in maximum current do not impact the safety and effectiveness due to

Description	ZIDA	URGENT PC UPC 200-A	Substantial Equivalence
K#	TBD	K071822	--
			the differing technological characteristics.

Garment Electrode

There are significant differences in the Urgent PC predicate needle electrode and the ZIDA Garment Electrode due to the different electrical current delivery to the nerve. The ZIDA electrode presents less potential for adverse events (infection, pain during insertion, improper positioning) than the needle electrode. Garment electrodes are effectively used for nerve stimulation with traditional TENS stimulators for pain; the differences in the ZIDA electrode when compared to the Urgent PC needle electrode do not present new issues of safety or effectiveness.

Both the subject and EMSI garment device support the same scientific methodology and are intended as single patient reusable garment electrodes to deliver electrical stimulation. The ZIDA garment is intended for use only with the ZIDA stimulator, while the EMSI device may be used with multiple devices. This difference does not present any new concerns for safety and effectiveness.

Description	**ZIDA**	**URGENT PC UPC 200-A**	**EMSI Garment Electrode (Reference Device)**
K#	TBD	K071822	K090889
Product Code	NAM	NAM	GXY Cutaneous electrode
Indication for Use and Intended Use	Embedded conductive garment electrode is interface between ZIDA stimulator (Control Unit) and patient skin for delivery of electrical stimulation	The Urgent PC Lead Set transfers electrical current from the stimulator via a Needle electrode	Electrodes intended for use as reusable (single patient) cutaneous, flexible, conductive garment/fabric electrodes for interface between electrical stimulators such as IF, galvanic, TENS, etc. and patient skin for delivery of electrical stimulation.
Description	The yarn of the conductive surface of the garment is 80% Nylon/20% Silver as a percentage by weight. The purity of silver used is 99.9% metallic silver with 100% electrode surface area coverage. The dimension of the		The EMSI Garment Electrodes are a cloth type device weft knitted of a continuous fiber made up of 77% Nylon and 23% Silver. Each device is flexible and is available in a range of sizes to ensure good patient contact. A male snap connector is placed

Description	ZIDA	URGENT PC UPC 200-A	EMSI Garment Electrode (Reference Device)
	top electrode and bottom conductive surface is 2cm X 4cm X 0.59cm. The wire connection is a sublimated transfer print that runs from ankle to the arch of heel. The non-conductive portions of the garment are made up of wool/cotton/nylon blend and double cover Lycra elastomer.		within the fabric weave and is connected via the female snap connector to a short lead wire. The lead wire has a female pin connection at the distal end which accepts the lead wire connection from the stimulator. The entire fabric is made up of conductive material to provide uniform current distribution when connected to a stimulator.
Connection type	Male and female snaps	Lead wire set	Snap and lead wire
Sizes	S, M, L, extra-L sock or tight	N/A	Multiple configurations and sizes based on intended area of use
Reusable	Single patient	N/A Sterile single use	Single patient
Washing validation	30 washes	N/A	30 washes
Patient contact	Intact skin	Percutaneous insertion	Intact skin
Biocompatibility	ISO 10993-5 and - 10	Unknown	ISO 10993-5 and - 10

Performance testing

The ZIDA System has been tested and conforms to the following applicable standards:

Standard
ANSI AAMI 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
ANSI AAMI IEC 60601-1-2 General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
IEC 60601-2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 10993-1 Evaluation and testing within a risk management process
ISO 10993-5 Tests for in vitro cytotoxicity
ISO 10993-10 Tests for irritation and skin sensitization
ISO 14971 Medical devices -- Application of risk management to medical devices
ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes
ASTM E3162-18 Standard Practice Measuring the Durability of Antibacterial Agents Applied to Textiles under Simulated Home Laundering Conditions
IEC 62366-1:2015 Medical Devices-Part 1: Application of usability engineering to medical devices

Usability

ZIDA usability testing was conducted in a simulated home use environment. The tester had access to the basic facilities and tools to effectively operate the device including reading the instructions and user guide. Fifteen (15) participants were provided the ZIDA Control Unit, a ZIDA embedded sock, instruction manual and quick start guide. Users had no prior training or exposure to the ZIDA device. The study results support the device labeling contains appropriate information for home use.

Clinical Data

Two clinical investigations of the ZIDA Wearable Neuromodulation System were conducted in the United States at a single center to obtain clinical information to demonstrate whether the device is substantially equivalent to the predicate device, the Urgent PC Neuromodulation System. The initial investigation enrolled 23 out of a planned 50 patient study but was stopped to amend the clinical protocol to obtain effectiveness information. After the protocol was amended, the second trial was launched enrolling 40 subjects. In total, 63 subjects, were randomized 1:1 to treatment with the device or sham-treatment with the device not activated.

The primary objective of the first study was to assess the Quality of Life (QoL) of subjects treated with the ZIDA device. The second study sought to determine whether the ZIDA device was substantially equivalent in terms of safety and effectiveness to the Urgent PC device in treating overactive bladder (OAB) symptoms of urinary urgency, urinary frequency, and urge incontinence. Subjects were diagnosed with OAB based on meeting the criteria defined by the International Continence Society, i.e., subjects with an average urinary frequency: ≥8 voids and ≥1 urgency episode (with or without incontinence) per 24 hours and who had a normal urinalysis and a score of 60 or higher on the Incontinence impact questionnaire-OAB-q Short Form, 4-week recall were considered eligible for the study. Subjects were provided the device and instructed to have once-weekly treatments of 30 minutes with the device for 12 consecutive weeks. The ZIDA device was self-administered by the subject at home. Participants reported 100% compliance with all weekly treatments for 12 weeks on both arms in both studies. In the second study, treatment success was defined as at least a 50% reduction in urinary urgency voids with or without incontinence or at least a 30% reduction in the frequency of daytime or nighttime voids from baseline to week 12. The treatment success rate in the ZIDA device arm was 80%, as compared to the treatment success rate of 39% in the sham control arm. Hence, the primary endpoint of the study was considered met. Subjects on the ZIDA device had a greater decrease in the number of urgent episodes from baseline to Week 12 as compared to subjects on sham control; a greater decrease in the number of incontinence episodes from baseline to Week 12 compared to sham control, and a greater decrease in the total number of voids per day from baseline to Week 12 compared to sham control. The study results from the second study based on the bladder diaries (urinary frequency, urinary urgency, and urinary incontinence) for the ZIDA device were similar to the results based on the bladder diaries reported in the studies evaluating the predicate Urgent PC device.

Two adverse events (AEs) were reported over the course of the first study, both in the sham control arm and both considered unrelated to the device. Five AEs were reported over the course of the second study: two subjects, both in the active ZIDA device arm, reported a mild AE of urinary tract infection which was not considered related to the study treatment; and two subjects, also both in the active ZIDA device arm,

reported an expected mild AE of pain in the foot during or immediately after treatment that resolved within half an hour of treatment cessation.

In both the first and second studies, quality of life was improved in subjects treated with the ZIDA device compared to those in the sham control arms. In the second study, subjects in the ZIDA device arm reported greater satisfaction with the ZIDA device and improvement of OAB symptoms than subjects in the sham control arm. Subjects in the ZIDA device group were more likely to recommend the device compared to those in the sham control group.

In summary, the clinical information obtained in the 2 studies indicates that the ZIDA device is substantially equivalent, in improving symptoms of urinary incontinence, urinary urgency, and total urinary frequency well as improving quality of life for subjects with overactive bladder, to the predicate device Urgent PC Neuromodulation System.

Conclusion

There are no differences between the subject device and the predicate with respect to indications and intended use. Technological differences in the predicates and subject devices do not present new issues of safety and effectiveness. Exodus has evaluated the benefit-risk profile of the ZIDA System in comparison to the predicate device in accordance with FDA's Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics, September 2018, as well as the risk and Special Controls identified in the Reclassification Order for K992069. The clinical trials and risk evaluation assessed the benefits and risk associated with the ZIDA (transcutaneous tibial nerve stimulator-TTNS) when compared to the Urgent PC (K071822), percutaneous tibial nerve stimulator- PTNS) in treating patients with Overactive Bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence by neuromodulation of the sacral nerve. The ZIDA TTNS has the same intended use as the predicate Urgent PC PTNS, and different technological characteristics which do not raise different questions of safety and effectiveness.

Beyond the general indications for use of the EMSI Garment Electrode (reference device), and the OAB specific indication of the ZIDA sock or tight, and lead wire to snap vs direct snap connection, the garment electrodes are utilized in the same method and testing has confirmed comparable performance. There is no difference in the ZIDA Garment Electrode and the EMSI Garment Electrode that present new issues of safety and effectiveness.

The ZIDA Wearable Neuromodulation System is substantially equivalent to the Urgent PC Neuromodulation System, K071822.