DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 10, 2017

International Trade Group, Inc.
Brent Reider
President & Secretary of International Trade Group, Inc.
4663 Katie Lane
Oxford, Ohio 45056

Re: K171092
Trade/Device Name: XiniWave II Model ECS322P
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NUH
Dated: February 2, 2017
Received: April 12, 2017

Dear Brent Reider:

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. 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171092

Device Name
XiniWave II Model ECS322P

Indications for Use *(Describe)*
TENS: The device is intended for the temporary relief of pain associated with sore and aching muscles in the lower back, upper extremities (arms) and lower extremities (legs) due to strain from exercise and/or normal household and work activities.

NMS: The device is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

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

General Information	As Required by 21 CFR 807.92(c)
Applicant Date:	26 April 2017
Applicant & Spec. Dev. Name:	International Trade Group, Incorporated
Applicant & Spec. Dev. Address:	4663 Katie Lane, Suite "O" Oxford, OH 45056 USA
Applicant & Spec. Dev. Tele.:	614-568-7000
Applicant & Spec. Dev. FAX:	614-568-7001
Applicant & Spec. Dev. Contact:	Brent C. Reider, President
Applicant & Spec. Dev. e-mail:	brent.reider@yarlap.com
Device Trade Name and Model:	**XiniWave II Model ECS322P**
510(k):	**K171092**
Common/Usual Name:	Stimulator, Nerve, Transcutaneous for Pain Relief Over-the-Counter Combined with Powered Muscle Stimulator, Over-the-Counter.
Classification Group:	NGX & NUH
Classification Name:	Stimulator, Nerve, Transcutaneous for Pain Relief Over-the-Counter Combined with Powered Muscle Stimulator, Over-the-Counter.
Classification regulations:	21CFR 882.5890 OTC: Stimulator, Nerve, Transcutaneous for Pain Relief 21CFR 890.5850 OTC: Powered Muscle Stimulator

Applicant Device Description

The Applicant device, **XiniWave II Model ECS322P**, is a precision Class II device housed in a sturdy lightweight cabinet. The keypad controls and the circuit for the Applicant device are identical to the Predicate. For a maturing user constituency, the cabinet of the Applicant device is larger than the Predicate with a bigger white paper Liquid Crystal Display (LCD), yet the weight of the device is virtually equivalent. The Applicant device is powered by 3 x 1.5V AAA alkaline batteries. The Applicant device offers the user a choice of eight (8) pre-set Transcutaneous Electro Neuro Stimulation (TENS) programs for the temporary relief of pain (80 mA Max.) and one pre-set Neuro-Muscular Electrical Stimulation (NMES) program for muscle conditioning (90 mA Max.). In the NMES mode of operation the user is able to select work/rest stimulation with pulse rates between 2−100Hz and pulse widths between 50−450µS rate may be selected. The mode of action for the Applicant device in TENS or NMES mode is identical to the mode of action to the Predicate.

The Applicant device is supplied with skin electrodes (electrode surface minimum of 25cm^2), to stimulate the patient. The skin electrodes (extant for the industry) are the same ones as supplied with the Predicate and delineated in the User's Manual. The Applicant device control unit connects directly to the skin electrode by cable and plug (extant for the industry).

Sold as a kit, the **XiniWave II Model ECS322P** kit consists of:

One (1) Battery Powered Stimulator (Control Unit)
One (1) set of Four (4) skin electrodes
Three (3x1.5V) AAA Batteries
One (1) User's Manual
One (1) case

Individual components that may be lost *(e.g.,* battery compartment door) or which must be replaced throughout normal usage (*e.g.,* battery and electrode(s) can be re-ordered individually, see User's Manual).

Predicate Device:
Per 21 CFR 807.92(a)(3), the cited Predicate device is:

Predicate Trade Name and Model:	**XiniWave, Model XW-18**
Predicate 519(k):	K100441
Predicate 510(k) Holder:	International Trade Group, Inc. (Applicant of XiniWave II Model ECS322P)
Predicate Product Code:	NGX & NUH
Predicate Common/Usual Name:	Stimulator, Nerve, Transcutaneous for Pain Relief Over-the-Counter Combined with Powered Muscle Stimulator, Over-the-Counter.
Predicate Classification Name:	Stimulator, Nerve, Transcutaneous for Pain Relief Over-the-Counter Combined with Powered Muscle Stimulator, Over-the-Counter.
Predicate Classification Reg.:	21CFR 882.5890 OTC: Stimulator, Nerve, Transcutaneous for Pain Relief 21CFR 890.5850 OTC: Powered Muscle Stimulator
Predicate Indications for Use:	Unchanged to Applicant Device
Predicate Essential Technology:	Unchanged to Applicant Device

Indications for Use

The indications for use of the Applicant device, see Section 5.0 table 1 below, are consistent with the uses described under 21CFR 882.5890 OTC: Stimulator, Nerve, Transcutaneous for Pain Relief and 21CFR 890.5850 OTC: Powered Muscle Stimulator.

Applicant & Predicate (K100441) Indications for Use (Unchanged) **Section 5.0 Table 1**
TENS: The device is intended for the temporary relief of pain associated with sore and aching muscles in the lower back, upper extremities (arms) and lower extremities (legs) due to strain from exercise and/or normal household and work activities. NMS: The device is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

Indications for Use Discussion

The indications for use of the Applicant device and the Predicate are unchanged and consistent with the uses described under 21CFR 882.5890 OTC: Stimulator, Nerve, Transcutaneous for Pain Relief and 21CFR 890.5850 OTC: Powered Muscle Stimulator.

Device Modifications

The device modifications listed in Section 5.0, Table 2, do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Device Modifications **Section 5.0, Table 2**		
Modification	**Predicate Device (K100441)**	**Applicant Device (TBA)**
Energy Type:	1 X 9 Volt Alkaline Battery (standard 800mAh)	3 X 1.5 Volt Alkaline Batteries (standard 1,000mAh)
	See Tables 3 & 4 later in this Section and Section 12.0, Tables 3 & 4 for Power Density details.	
Ergonomics:	Paper White LCD - 35 X 17 mm	Paper White LCD - 45 X 35 mm
	Weight: 0.09 kg. without battery, 0.1 kg. with battery.	Weight: 0.12 kg. without battery, 0.16 kg. with battery.
	Channel Outlet/Connectors on Cabinet Top	Channel Outlet/Connectors at Cabinet Base
	Electrode Positioning Belt for Lower Back	No Electrode Positioning Belt for Lower Back
Dimensions:	108 X 62 X 23 mm. without clip	128 x 67 x 25 mm. without clip
Software†:	TENS: All 7 Programs are Pre-set NMES: All 6 Programs are Pre-set	TENS: All 8 Programs, Pre-set NMES: 1 Program, User Select In NMES Mode user is able to select work/rest stimulation with rates between 2−100Hz & width between 50−450μS
	Program Run Times are Pre-set	Program Run Times Pre-Set Incremental to Max. Program Lock Feature to set and record 1 program
Manual:	English	English & Spanish
† The Applicant and Predicate devices are programmed exactly the same way, by hardwire connection to the Circuit Board using identical secure proprietary software codes. Neither the Applicant nor the Predicate device can be programmed by remote radio frequency signals. Electro Magnetic Certification of the device is presented in Section 17.1 of this Application		

Device Substantial Equivalence and Safety

The device modifications do not alter the fundamental scientific technology of the device under 21CFR 882.5890 OTC: Stimulator, Nerve, Transcutaneous for Pain Relief and 21CFR 890.5850 OTC: Powered Muscle Stimulator. The Applicant device uses

Substantially Equivalent programs as the Predicate device (per 21CFR 882.5890 OTC and 21CFR 890.5850 OTC). Program comparisons for the Applicant and Predicate are demonstrated in Section 5.0, Table 3 below:

Device Substantial Equivalence and Safety of the Applicant and Predicate Programs
Section 5.0, Table 3

Program Description			Rate Hz	Pulse µS	Work Sec.	Rest Sec.	Time Min.	Max. mW/cm² 80mA	Max. mW/cm² 90mA	Ave. mW/cm² 45 mA
Utility	Predicate K100441	Applicant						Electrode Surface Min. of 25cm² Assumes 500 Ohm Load		
Applicant Device has 8 TENS Programs (3 are HAN/TENS) – The Predicate Device has 7 TENS Programs										
TENS	Program 1		80	200	n/a	n/a	60	2.0	n/a	0.6
HAN		Program 1	2/70	260/150	n/a	n/a	30	1.3	n/a	0.4
Predicate & Applicant are similar										
TENS	Program 2		50	100	n/a	n/a	60	0.6	n/a	0.2
HAN		Program 2	2/15	260/180	n/a	n/a	30	0.3	n/a	0.1
Predicate & Applicant are similar										
TENS	Program 3		10	175	n/a	n/a	60	0.2	n/a	0.1
HAN		Program 3	2/100	260/130	n/a	n/a	30	1.7	n/a	0.5
Predicate & Applicant are similar										
TENS	Program 4		150	200	n/a	n/a	60	3.8	n/a	1.2
		Program 4	2/200	50/300	n/a	n/a	60	7.7	n/a	2.4
Predicate & Applicant are different										
TENS	Program 5		150	175	n/a	n/a	60	3.4	n/a	1.1
		Program 5	150	200	n/a	n/a	60	3.8	n/a	1.2
Predicate & Applicant are similar										
TENS	Program 6		100/65	200/100	n/a	n/a	60	2.6	n/a	0.8
		Program 6	100	120	n/a	n/a	60	1.5	n/a	0.8
Predicate & Applicant are similar										
TENS	Program 7		65/10	200/100	n/a	n/a	60	1.7	n/a	0.5
		Program 7	35	200	n/a	n/a	60	0.9	n/a	0.3
Predicate & Applicant are similar										
TENS										
		Program 8	10/15	150/250	n/a	n/a	55	0.5	n/a	0.2
Applicant Device has only 1 NMES Program – The Predicate Device has 6 NMES Programs										
MNES	Program 9		35	250	8	8	15	n/a	1.4	0.4
		Program 9	2/90	50/450	User Variable		15	n/a	6.5	1.6
Predicate & Applicant are different										

While the identified program output differences appear evocative, the output of the applicant are within extant mode of clinical effectiveness and devices cleared in 21CFR 882.5890 OTC: Stimulator, Nerve, Transcutaneous for Pain Relief and 21CFR 890.5850 OTC: Powered Muscle Stimulator. Additional information has been included in the manual for the user to better understand and optimally managing the fundamental scientific technology of the device. In this way a lay-person seeking pain management therapy and muscle conditioning can derive maximum benefit from the output potential of the device.

The Applicant and Predicate devices are programmed by hardwire connection to the Circuit Board only. Neither the Applicant nor the Predicate device can be programmed

by remote radio frequency signals. The product firmware is written in a secure (proprietary) code.

The skin electrode in the Applicant device is identical to the Predicate device. The Applicant device control unit connects directly to the skin electrode by cable and plug (design extant for the industry).

Water–resistance is designed into the unit for EU mandated performance requirements per IEC 60601-2-11:2013 only. To the Applicants knowledge, it is not the custom to use any device of this type in wet areas. The Applicant is in complete agreement with FDA guidance not to use the device in wet areas. Hence, the Applicant device will not be promoted as water-resistant nor labelled as such per this 510(k) submission.

The manual of the Applicant and Predicate devices are printed in English. The Applicant device is available in Spanish. The Spanish test is available on request. The languages used in the Applicant device have been selected based on the predominant languages spoken in the United States and Commonwealth of Puerto Rico and then cross-referenced with the cumulative immigration data selecting the three largest languages spoken by immigrant populations to enter theses United States over the past 50 years (1965 to 2015). As such the device labelling complies with or exceeds 21 CFR 801.15(a)(6)(3)(c)(1)(2)& (3).

The Risk Assessment prepared by an independent firm and reviewed by independent commentators, in accordance with the Quality System Regulation (including documentation of design inputs, risk analysis, design output, test procedures, verification and validation procedures, and documentation of formal design reviews) demonstrate that the product modifications are as safe, and effective, and that the Applicant device performs as well as the Predicate device [21 CFR 807.92(b)(3)].

The Applicant device uses the identical pre-set NMES programs as the Predicate device and such, the out-put, in the applicable NMES programs is substantially equivalent as demonstrated in Section 5.0 Table 4 below.

Device Substantial Equivalence and Safety
Applicant and Predicate Out-put by NMES Program
Section 5.0 Table 4

Basic Unit Characteristics	Applicant Device XiniWave	Applicant Device XiniWave II
510(k)	**K100441**	**To Be Advised**
Maximum Output Current pulse peak @ 500 Ohms	80mA +0/- 8%	TENS 80mA +0/- 8% NMES 90mA +0/- 8%
Maximum Output Current pulse peak @ 2K Ohms	50mA +/-10%	50mA +/-10%
Maximum Output Current pulse peak @ 10K Ohms	19mA +/-10% And thus shuts off	19mA +/-10% And thus shuts off

Pulse Width (µS)	175 µS – 250 µS, program dependent	50 µS – 250 µS, program dependent
Frequency (Hz)	12 Hz - 150Hz, program dependent	2 Hz - 100Hz, program dependent
Net Charge @ 500 ohms (µC per pulse) (If zero, state method of achieving zero net charge.)	Zero- positive pulse is equal and opposite to negative pulse. Asymmetrical DC zero (Transformer output)	Zero- positive pulse is equal and opposite to negative pulse. Symmetrical DC zero (Transformer output)
Maximum (Peak) Phase Charge, (µC) at 500 ohms	80mA x 250µS = 20 µC This corresponds to the longest pulse at the highest current.	90mA x 450 µS = 40 µC This corresponds to the longest pulse at the highest current.
Maximum (peak) Current Density, (mA/cm²) 2 X 2	3.2 mA/cm^2 Surface = 25 cm² (2X2)	4.3 mA/ cm^2 Surface = 25 cm² (2X2)
Maximum Power Density, (W/cm²) at 500 ohms	3.8mW/ cm^2 At maximum frequency of 150Hz pulse width 200µS and current of 80mA.	7.7 mW/ cm^2 At maximum frequency of 100Hz pulse width 450µS and current of 90mA. TENS Program 04

Therefore, since the device modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device concordant with the uses described under 21CFR 882.5890 OTC and for muscle conditioning as described under 21CFR 890.5850 OTC: Powered Muscle Stimulator (i.e., Indications for Use unchanged from the Predicate) and the Quality Assurance paradigm, including Risk, demonstrates that the product modifications are as safe, and effective, and performs as well as or better than the Predicate device. As such the Applicant device and does not raise new questions about safety or effectiveness and demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as a legally marketed device.

Conclusion

- The Applicant device is substantially equivalent to the predicate because it has the same intended therapeutic use as the Predicate described under 21CFR 882.5890 OTC: Stimulator, Nerve, Transcutaneous for Pain Relief and 21CFR 890.5850 OTC: Powered Muscle Stimulator;
- The Applicant device has the similar technological characteristics as the Predicate and that any differences do not adversely impact the safety or effectiveness of the Applicant device;
- The therapeutic labelling of the Applicant device is concordant with the Predicate and
- The information submitted to the FDA for the Applicant device does not raise new questions about safety or effectiveness and demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as the Predicate, a legally marketed device.

Hence, the **XiniWave II Model ECS322P** device meets the FDA's definition of Substantial Equivalency under the relationships cited above (21 U.S.C. §§ 360(n), 360c(f)(1) & 360c(i); 21 CFR 807.92(a)(3) and suggest when obtained over-the-counter and used by a layperson without oversight by a healthcare practitioner in a non-clinical environment, the applicant device can be used correctly, safely and in a manner that produces temporary pain relief consistent with the uses described under 21CFR 882.5890 OTC and for muscle conditioning as described under 21CFR 890.5850 OTC: Powered Muscle Stimulator.