DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 24, 2015

International Trade Group, Inc.
Brent C. Reider
President
4663 Katie Lane, Suite O
Oxford, OH 45056

Re: K141643
Trade/Device Name: Yarlap
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: March 31, 2015
Received: April 1, 2015

Dear Brent C. 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 yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K141643

Device Name

YARLAP

Indications for Use *(Describe)*

The device is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

General Information	As Required by 21 CFR 807.92(c)
Date Prepared	31 March 2015
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:	info@internationaltradegroup.info
Trade Name of Device:	**YARLAP**
510(k):	**K141643**
Common/Usual Name:	Battery Powered Muscle Stimulator with Vaginal Electrode, Non-Implantable, For Pelvic Floor Muscle Conditioning, Prescription and Over-The-Counter (OTC).
Classification Group:	KPI
Classification Name:	Stimulator, Electrical, Non-Implanted for incontinence.
Classification regulation:	21 CFR 876.5320

Predicate Devices:
Per 21 CFR 807.92(a)(3), the two predicate (ProCode: KPI) devices are:

- **Kegel8** Pelvic Muscle Exerciser Model OPH 400 by N.E. Services, Limited
  - **K-081480**
- **NuTrac Pelvator** Model PEL 200 by Verity Scientific Limited
  - **K-083704**

Applicant Device Description:
The Applicant device, **YARLAP**, is a precision Class II device housed in a sturdy lightweight cabinet. The device is battery powered with a backlit Liquid Crystal Display (LCD) and offers the user a choice of six (6) pre-set Neuromuscular Electrical Stimulation (NMES) programs. The NMES programs are Work/Rest modes of operation. The Applicant device has no TENS programs. The Applicant device is supplied with a vaginally inserted electrode specifically designed in 2003 for the hardware, circuit and software used in device to stimulate the female *pubococcygeus (PC)* muscle. The Applicant device control unit connects directly to the design-specific electrode by cable and plug (extant for the industry).

Sold as a kit, the **YARLAP** kit consists of:

One (1) Battery Powered Muscle Stimulator (Control Unit)
One (1) vaginally inserted electrode specifically designed for the hardware, circuit and software used in the Control Unit to stimulate the female *pubococcygeus (PC)* muscle.
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).

Indications for Use:
The device is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

Differences in Indications for Use Discussion:
A comparison of the applicant and predicate(s) stated Indications for Use (IFU) is below:

Table of Comparative Indications for Use	
Predicate Device(s)	**Applicant Device**
The device is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of treat stress, urge and mixed incontinence in women.	The device is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

The indications for use treat stress, urge and mixed incontinence in women and to maintain urinary continence in women may be considered reasonably consistent with the use described under 21 CFR 876.5320 in maintaining "continence" because in the conveyance of electrical stimulation to treat stress, urge and mixed incontinence in women and the mutual promotion continence by posture of the visceral organs and response to inter-abdominal pressure are concordant and do not introduce "different technological characteristics," and demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as a legally marketed device (see below). [1]

Device Substantial Equivalence and Safety
The primary function of the PC muscle is postural (i.e., muscle tone affects postural control - keeping the visceral organs in position [see stress incontinence below] and postural stability). Additionally, the PC muscle responds to inter abdominal (urinary) cues (*e.g.,* start and stop).

[1] "While a new device must have the same intended use as a predicate device in order to be SE, the Centre does not require that a new device be labelled with precise therapeutic or diagnostic statements identical to those that appear on predicate device labelling in order for the new device to have the same intended use" 21 U.S.C. §§ 360(n), 360c(f)(1) & 360c(i); 21 CFR 807.92(a)(3)) per extant Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3.

The FDA has cleared many substantially equivalent devices for the treatment of stress, urge and mixed urinary incontinence in women using the NMES modes with a vaginally inserted electrode. This is the exact mode of action in the applicant device and of the Predicate (I) device: KEGEL8 Pelvic Muscle Exerciser Model OPH 400 (K081480) and Predicate (II) device: NuTrac Pelvator Model PEL 200 (K083704).

The biocompatible materials, circuit, hardware, software, construction and vaginally inserted electrode in the Applicant device, YARLAP, are identical to those used in the Predicate (I) device, KEGEL8 (K081480). As such, the Applicant device, "**YARLAP**," is substantially equivalent to:

- **Kegel8** Pelvic Muscle Exerciser Model OPH 400 by N.E. Services, Limited
  - **K-081480**
  - Product Code: KPI

The biocompatible materials, safety features and vaginally inserted electrode in the Applicant device, YARLAP, are identical to those used in the Predicate (II) device, NuTrac Pelvator Model PEL 200 (K083704). The hardware, software and construction are substantially similar. As such, the Applicant device, "**YARLAP**," is substantially equivalent:

- **NuTrac Pelvator** Model PEL 200 by Verity Scientific Limited
  - **K-083704**
  - Product Code: KPI

The applicant device uses only pre-set substantially equivalent programs at only the most common (and intermediate) out-put levels of the cited predicates (see tables 1 & 2 below).

Additional Information Request Table 1			
Basic Unit Characteristics	**Predicate (II) Device NuTrac Pelvator**	**Predicate (I) Device Kegel 8**	**Applicant Device YARLAP**
510(k)	**K083704**	**K081480**	**K141643**
Maximum Output Current pulse peak @ 500 Ohms	90mA +0/- 8%	90mA +0/- 8%	80mA +0/- 8%
Maximum Output Current pulse peak @ 2K Ohms	50mA +/-10%	50mA +/-10%	50mA +/-10%
Maximum Output Current pulse peak @ 10K Ohms	19mA +/-10% And thus shuts off	19mA +/-10% And thus shuts off	19mA +/-10% And thus shuts off
Pulse Width (µS)	50 µS – 330 µS, program dependent	50 µS – 450 µS, program dependent	200 µS – 250 µS, program dependent
Frequency (Hz)	2 Hz - 100 Hz, program dependent	2 Hz - 100 Hz, program dependent	10 Hz - 35Hz, 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. Symmetrical DC zero (Transformer output)	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. Asymmetrical DC zero (Transformer output)
Maximum (Peak) Phase Charge, (µC) at 500 ohms	90mA x 330 µS = 27.9 µC This corresponds to the longest pulse at the highest current.	90mA x 450 µS = 40.5 µC This corresponds to the longest pulse at the highest current.	80mA x 250 µS = 20 µC This corresponds to the longest pulse at the highest current.

Maximum (peak) Current Density, (mA/cm²) Vaginal	14.1 mA/sq. cm Surface = 6.4 cm²	14.1 mA/sq. cm Surface = 6.4 cm²	12.5 mA/sq. cm Surface = 6.4 cm²
Maximum (peak) Current Density, (mA/cm²) 2 X 2	3.6 mA/sq. cm Surface = 25 cm² (2X2)	3.6 mA/sq. cm Surface = 25 cm² (2X2)	3.2 mA/sq. cm Surface = 25 cm² (2X2)
Maximum Power Density, (W/cm²) at 500 ohms	41.8 mW/sqcm At maximum frequency of 100Hz, pulse width 330µS and current of 90mA (Custom: PC1, PC2, & PC3) PC Electrode area: 6.4 cm²	28 mW/sqcm At maximum frequency of 100Hz, pulse width 450µS and current of 90mA (Custom: PC1, PC2, & PC3) PC Electrode area: 6.4 cm²	3.5 mW/sqcm At maximum frequency of 35Hz pulse width 200µS and current of 80mA. (P06) PC Electrode area: 6.4 cm²

So, while Maximum Power Density is a near ten fold difference (tables above) the true comparative Maximum Power Density for the Applicant device is established by comparing the out-put of the pre-set intermediate programs of the predicate with the corresponding pre-set programs of the applicant device. As the table below demonstrates, the values are substantially equivalent when comparing the power density of the pre-set programs at the recommended starting/ beginners intensity level of 30mA, as well as at the user intensity level of 45mA or at the maximum possible intensity level of each comparative program (see the three columns to the far right of the Table 2 below).

Additional Information Request Table 2

Utility	K141643 Applicant 80mA	K081480 Predicate 90mA	Rate	Pulse	Work	Rest	Time	Max. W/cm² 80 vs 90	Ave. W/cm² 30mA	Ave. W/cm² 45mA
Mixed	Program 1		12	200	5	5	15	1.2	0.17	0.38
		Program 5	10	200	5	5	20	1.3	0.14	0.32
Mixed	Program 2		20	250	8	8	20	2.5	0.35	0.79
		Program 9	20	250	5	5	20	3.2	0.35	0.79
Urge	Program 3		12	200	5	10	15	1.2	0.17	0.38
		Program 2	10	250	5	5	20	1.6	0.18	0.39
Urge	Program 4		10	200	6	12	20	1.0	0.14	0.32
		Program 5	10	200	5	5	20	1.3	0.14	0.32
Stress	Program 5		12	250	5	15	15	1.5	0.21	0.47
		Program 2	10	250	5	5	20	1.6	0.18	0.40
Stress	Program 6		35	200	6	18	20	3.5	0.50	1.11
		Program 3	40	200	6	15	20	5.1	0.56	1.26
For the Applicant [K141643] programs chart see page 14 of the Yarlap manual.										
For the Predicate [K081480] programs chart see page 12 of the Kege8 manual.										

As such:

1. the applicant device has the same technological characteristics as the predicate; and
2. 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 a legally marketed device.

The predicates provide safe and effective stimulation to treat stress, mixed and urge incontinence in women using pre-set and custom [programmable] settings. The custom [programmable] settings in the predicate have broad out-put capabilities and as such the Maximum Power Density for the predicates reflect this fact (i.e., for the K081480; 28 mW/cm^2 at a maximum frequency of 100Hz, pulse width 450µS and current of 90mA). While all the programs of the predicate are unquestionably safe and effective; the higher-level power out-puts of the predicate custom [programmable] settings are rarely used. Indeed, the most widely used programs in the predicate are the pre-set intermediate out-put level programs. So, limiting the out-put levels in the applicant [OTC] device to the most widely used intermediate levels found in the pre-set programs of the predicate device(s) gives the applicant device the same technological characteristics as the predicate with commensurate efficacy, safety and reduced risk.

Vaginal Electrodes Substantial Equivalence and Safety:
The vaginally inserted electrode cited with both Applicant and Predicate devices was designed specifically for these devices. As such the electrode does not introduce "different technological characteristics" when used for treating urinary incontinence or when avoiding it.

Usability Study to Support OTC Use
Safety and efficacy of the device among racially diverse incontinent adult females un-familiar with the device was collected demonstrating that users were able to use the device correctly (successful task completion) and in a manner that produced strong tolerable pelvic floor contractions. Both the observer and subject participants were charged with annotating possible improvements to the device itself or its labelling as well as documenting any specified or unspecified actual or potential hazard(s) concerning use, including, but not limited to the user's understanding of the device from the packaging, the user's comprehension of the instructions, the user's selection of an appropriate intensity level, or cleaning and storage.

All aspects of OTC usability were positive including, but not limited to the user's operative understanding of the device, the user's comprehension of the labelling, including the packaging and instructions, the user's selection of an appropriate intensity level and storing the device after completion of treatment. No adverse events were observed nor were potentially hazardous situations observed or prognosticated when the participants followed the provided labelling on an OTC basis.

Conclusion

- The applicant device is substantially equivalent to the predicate because it has the same intended use as the predicate;
- The applicant device has the same technological characteristics as the predicate;
- The labelling of the applicant device is concordant with the predicate and FDA compliant 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 a legally marketed device.

- The results of the Usability Study demonstrate the device can be used by a lay-person without medical professional oversight on an OTC basis for the rehabilitation of weak pelvic floor muscles to treat stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

The YARLAP 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 the indications 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 manor that produces strong tolerable pelvic floor muscle contractions appropriate for the user's condition to treat stress, urge or mixed incontinence in women and/or to maintain urinary continence in women.