DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 4, 2016

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

Re: K160773
Trade/Device Name: Yarlap II
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: Class II
Product Code: KPI, HCC
Dated: February 29, 2016
Received: March 21, 2016

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 yours,

Herbert P. Lerner -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

Indications for Use Statement

510(k) Number (if known): K160773

Device Name: **"YARLAP II" Model ECS323P**

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.

Prescription Use ____X_____ AND/OR Over-The-Counter Use_____X_____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Summary

General Information	As Required by 21 CFR 807.92(c)
Date Prepared	3 May 2016, Tuesday
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:	**YARLAP II, Model ECS323P**
510(k):	**K160773**
Common/Usual Name:	Battery powered nonimplanted electrical continence device with Biofeedback. Prescription and Over-The-Counter (OTC).
Classification Group:	KPI & HCC
Classification Name:	Nonimplanted electrical continence device with Biofeedback
Classification regulation:	21 CFR 876.5320: Nonimplanted electrical continence device 21 CFR 882.5050: Biofeedback device

Applicant Device Description

The Applicant device, **YARLAP II, Model ECS323P**, is a portable precision Class II device housed in a sturdy lightweight shock- and water-resistant cabinet with stylus. The device is battery-powered with a full color touch screen Liquid Crystal Display (LCD) and offers the user a choice of six pre-set Neuro-Muscular Electrical Stimulation (NMES) programs with four pre-set biofeedback response-based sound-enriched games. The NMES programs in the Applicant device are Work/Rest modes of operation and identical to the programs in the Predicate. The four biofeedback programs in the Applicant device are to facilitate user graduation from "muscle stimulation" to patient-initiated muscle contractions (*i.e.,* "true exercise"). Neither the Applicant device nor the Predicate have a TENS program. Bluetooth in the Applicant device facilitates gaming and therein patient-initiated "exercise" by permitting use of a larger external Bluetooth compatible display (*e.g.,* computer screen or television). The Bluetooth signal is out-going only. Any external Bluetooth-capable display is optional and is not supplied with the unit. The Applicant device is supplied with a vaginally inserted electrode used with the device to stimulate the muscle of the female pelvic floor (the electrode, essential technology and intended use are identical to the Predicate: K141643). The Applicant device is supplied with a biofeedback reference lead wire with a skin electrode(s). The Applicant device control unit connects directly to the vaginal electrode and reference wire by cable and plug (design extant for the industry).

Sold as a kit, the **YARLAP II, Model ECS323P** kit consists of:

One (1) battery-powered nonimplanted electrical continence device with biofeedback (Control Unit) with stylus
One (1) vaginally-inserted electrode specifically designed for the hardware, circuit and software used in the Control Unit to stimulate the female *pelvic floor* muscles.
One (1) biofeedback lead wire with (1 X 2" X 2") skin electrode
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 or the User's On Screen Video Manual).

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

Predicate Trade Name and Model:	Yarlap, Model ECS 323
Predicate 510(k):	K141643
Predicate 510(k) Holder:	International Trade Group, Inc. (Yarlap II Applicant)
Predicate Product Code:	KPI
Predicate Common/Usual Name:	Nonimplanted electrical continence device Prescription and Over-The-Counter (OTC).
Predicate Classification Name:	Nonimplanted electrical continence device
Predicate Classification Reg.:	21 CFR 876.5320
Predicate Indications for Use:	Unchanged to Applicant Device
Predicate Essential Technology:	Unchanged to Applicant Device

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.

Indications for Use Discussion

Table of Comparative Indications for Use (Unchanged) **Section 5.0 Table 1**
Predicate Device and Applicant Device Indications for Use are Identical
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 are consistent with the use described under 21 CFR 876.5320 and identical to the predicate. The biofeedback programs (programs 7 to 10) enable the user to bridge muscle stimulation (as defined by 21 CFR 876.5320) with patient-initiated muscle contractions (i.e., "true exercise"). Therefore maintaining continence with pelvic floor muscle control exercise is well within the purview of 21 CFR 876.5320 and thus concordant and unchanged from the Predicate.

Device Modifications

The device modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device therefore initially qualify as appropriate for review as a Special 510(k) under 21 CFR 807.87. All device modifications are listed below in Section 5.0, Table 2:

Device Modifications **Section 5.0, Table 2** Appropriate for review as a Special 510(k) under 21CFR 807.87		
Modification	**Predicate Device K141643**	**Applicant Device K160773**
Energy Type:	1 X 9 Volt Alkaline Battery (standard 800mAh)	4 X 1.5 Volt Alkaline Batteries (standard 900mAh)
	See the program table in Section 5.0, Table 4 for Power density details.	
Ergonomics:	Paper White LCD	Full Colour Video LCD
	Push Button Controls	Push Button & Touch Screen Controls with Stylus
	No Sound	Sound (Mute [0] and ten [1 to 10] sound level options)
	Printed Manual English	Printed Manual & Full Colour Video with Sound Narration English, Spanish & Chinese
	Not Water Resistant	Water Resistant (per IEC 60601-2-11:2013)
Dimensions:	108 X 62 X 23 mm	135 X 68 X 25 mm
Software:	"C" language, No Bluetooth	"C" language With Bluetooth †
	No biofeedback	Biofeedback
	See the program table below for voluntary unassisted contraction biofeedback information.	
Firmware: Waveform	Asymmetrical Biphasic DC zero	Symmetrical Biphasic DC zero
† Bluetooth signal is outgoing only. The Applicant and Predicate devices are programmed exactly the same way, by hardwire connection to the Circuit Board using software with identical security codes. Neither the Applicant nor the Predicate device can be programmed by remote radio frequency signals.		

Device Substantial Equivalence and Safety

The device modifications in the Applicant device have been introduced to encourage and facilitate the user to transition from "muscle stimulation" to "true exercise" and do not affect the intended use of the device. The NMES programs (programs 1 to 6) provide muscle stimulation concordant with the use described under 21 CFR 876.5320. These programs are identical to the Predicate and the power density out-put of the device is identical to the Predicate. The biofeedback programs (programs 7 to 10) enable the Applicant device to bridge muscle stimulation (as defined by 21 CFR 876.5320) with patient-initiated muscle contractions (i.e., "true exercise") to achieve the same unchanged indications for use under 21 CFR 876.5320. These program comparisons are 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. W/cm² 80 mA	Ave. W/cm² 30 mA	Ave. W/cm² 45 mA
Utility	Predicate K141643	Applicant								
Mixed	Program 1		12	200	5	5	15	1.2	0.17	0.38
		Program 1	12	200	5	5	15	1.2	0.17	0.38
Mixed	Program 2		20	250	8	8	20	2.5	0.35	0.79
		Program 2	20	250	8	8	20	2.5	0.35	0.79
Urge	Program 3		12	200	5	10	15	1.2	0.17	0.38
		Program 3	12	200	5	10	15	1.2	0.17	0.38
Urge	Program 4		10	200	6	12	20	1.0	0.14	0.32
		Program 4	10	200	6	12	20	1.0	0.14	0.32
Stress	Program 5		12	250	5	15	15	1.5	0.21	0.47
		Program 5	12	250	5	15	15	1.5	0.21	0.47
Stress	Program 6		35	200	6	18	20	3.5	0.50	1.11
		Program 6	35	200	6	18	20	3.5	0.50	1.11
			µV: Min-Max		**Cont. Sec.**	**Relax Sec.**	**Min.**	**Power Density Out-Put Not Applicable for Biofeedback**		
Biofeedback	None	Bunny Program 7	**Voluntary Unassisted Contraction: Pre-Set at 6 sec. + 10 sec. Relax**							
			0.3-2000 µV		2-10	2-10	16	Not Applicable		
	None	Rose 1 Program 8	**Voluntary Unassisted Contraction: Pre-Set at 6 sec. + 10 sec. Relax**							
			0.3-2000 µV		2-10	2-10	16	Not Applicable		
	None	Rose 2 Program 9	**Voluntary Unassisted Contraction: Pre-Set at 6 sec. + 10 sec. Relax**							
			0.3-2000 µV		2-10	2-10	16	Not Applicable		
	None	Bird Program 10	**Voluntary Unassisted Contraction: Pre-Set at 6 sec. + 10 sec. Relax**							
			0.3-2000 µV		2-10	2-10	16	Not Applicable		

Note: The minimum µV (true) cannot effectively go below 0.3 µV per system noise and other electrical noise.

Bluetooth Note:

The purpose of Bluetooth is to send a live biofeedback signal to a larger Bluetooth-compatible video display so the patients can see their performance in real time on a larger screen if desired. Instructions for Bluetooth and all capabilities of the Applicant device are in the printed manual and instructional video for the Applicant device.

The bio-feedback feature (programs 7 to 10) is an accessory that *supplements* the performance of the parent device (i.e., the treatment of female urinary incontinence in out-put NMES programs 1 to 6) because bio-feedback adds a new way of using the device without changing the intended use of the parent device (i.e., the performance of the accessory is defined under 21 CFR 882.5050). Furthermore, since the indications for use are unchanged from the Predicate the use and risk of the Applicant device, with the accessory, may be considered reasonably consistent and unchanged from the Predicate. The Applicant device allows the user to graduate from muscle stimulation to low-impact exercise.

The Applicant and Predicate devices are programmed exactly the same way, by hardwire connection to the Circuit Board. 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 applicant device has a unique, high level security system that monitors and controls the incoming and outgoing electronic traffic based on predetermined security rules will not allow stimulation during the use of any gaming (Biofeedback) programs (*i.e.,* the device will not allow a game program to be engaged during a NMES program). Conversely, a user cannot start muscle stimulation (NMES programs 1 to 6) without first exiting (full stop) the game program mode. A patent has been filed for this unique security in the Applicant device.[4] The product firmware does not contain any games. The games are coded into the file of a *micro* Secure Digital (SD) card only.

The biocompatible materials, and vaginally inserted electrode in the Applicant device, **YARLAP II, Model ECS323P** are identical or substantially equivalent (*See Table 2*) to the predicate device: Yarlap, Model ECS 323 (K141643). Power density for both skin and vaginal electrodes was calculated in the Predicate 510(k) and are recapped here below and recounted in Section 12.0 Substantial.

The Risk Assessment prepared by an independent firm and reviewed by independent commentators,[5] 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.

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[4] See YARLAP II KPI Special 510(K) Application Section 16.9 Software Non Provisional US Patent. The applicant device is unique in that the applicant device security system that monitors and controls the incoming and outgoing traffic based on predetermined security rules prohibits in any way the biofeedback programming to change TENS or NMES (mA) out-put, when in the TENS or NMES mode of operation, or to change/deliver an out-put when the device is operating in the biofeedback mode. There is no TENS mode of operation in any Yarlap device. The Applicant believes that an OTC device for the female pelvic floor should not have TENS capabilities.

[5] No author, nor commentator of the Risk Management File (see Section 16.0) is an officer, employee or shareholder of the Risk study sponsor and this Special 510(k) Applicant, International Trade Group, Inc.).

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 identical 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 YARLAP	Applicant Device YARLAP II
510(k)	**K141643**	**K160773**
Maximum Output Current pulse peak @ 500 Ohms	80mA +0/- 8%	80mA +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)	200 µS – 250 µS, program dependent	200 µS – 250 µS, program dependent
Frequency (Hz)	10 Hz - 35Hz, 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. 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 250 µS = 20 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	12.5 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	3.2 mA/sq. cm Surface = 25 cm² (2X2)	3.2 mA/sq. cm Surface = 25 cm² (2X2)
Maximum Power Density, (W/cm²) at 500 ohms	3.5 mW/sqcm At maximum frequency of 35Hz pulse width 200µS and current of 80mA. (P06) 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

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 use described under 21 CFR 876.5320 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 the Applicant device is appropriate for review as a Special 510(k) under 21CFR 807.87 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 use under 21 CFR 876.5320 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
- 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 **YARLAP II, Model ECS 323 P** device meets the FDA's definition of Substantial Equivalency under the relationships cited above (21 U.S.C. §§ 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 to maintain urinary continence in women.