DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 7, 2017

Everyway Medical Instrument Co., Ltd.
Robert Tu
President and Operator Owner
3FL., No. 5, Lane 155, Section 3, Beishen Rd.
Shenkeng Dist, New Taipei City, Taiwan 22203
R.O.C.

Re: K161349
Trade/Device Name: Everyway Incontinence Stimulation System
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: June 6, 2017
Received: June 7, 2017

Dear Robert Tu:

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,

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

EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
3Fl., No. 5, Lane 155, Sec. 3,Beishen Rd, Shenkeng Dist, New Taipei City, Taiwan,

Indications For Use

510(k) Number (if known): K161349

Device Name: Everyway Incontinence Stimulation System

Indications For Use:

Everyway Incontinence Stimulation System 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 _____ OR Over-The-Counter Use __√__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 at July 06, 2017.

The assigned 510(k) number is: K161349 .

1. Submitter's Identifications:
   Establishment: EVERYWAY MEDICAL INSTRUMENTS CO., LTD.
   Address: 3Fl., No. 5, Lane 155, Sec. 3, Beishen Rd., Shenkeng Dist, New Taipei City 222, Taiwan
   Registration Number: 9616877
   Operations: Manufacturer

   Owner/Operator: EVERYWAY MEDICAL INSTRUMENTS CO., LTD.
   Address : 3Fl., No. 5, Lane 155, Sec. 3, Beishen Rd., Shenkeng Dist, New Taipei City 222, Taiwan
   Contact Person: Robert Tu
   Phone : 886-2-2662-0038
   Fax No: 886-2-2664-5566
   e-mail : robert@everyway-medical.com

2. Name of the Device:
   Everyway Incontinence Stimulation System

3. Information of the 510(k) Cleared Device (Predicate Device):
   K141643: Yarlap Nonimplanted electrical continence device.
   K122194: Life-Care Vaginal Probe models PR-02A, PR-03A, PR-04A, PR-14A (for reference)
   K071951:Everyway Comfy EMS/Model EV-805(for reference)

4. Classification Information:

   Trade/Device Name: Everyway Incontinence Stimulation System
   Regulation Number: 21 CFR Part 876.5320
   Regulation Name: Stimulator, Electrical, Non-implantable, For Incontinence.
   Regulatory Class: II
   Product Code: KPI

5. Device Description:

   The Everyway Incontinence Stimulation System is a dual channel powered muscle stimulator 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 EV-805I stimulator is basically an Everyway's existing K071951-510(K) cleared model for power muscle stimulator. To make it delivery the same stimulation output as that of chosen predicate device, we made some change in software so as to generate muscle stimulation current that is discharged through the PR-02A, PR-03A, PR-04A, PR-14A Life-Care Vaginal Probe on the vaginal skin for the treatment of urinary incontinence.

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The device is operated in such a way that turn on the intensity control knob and adjust the intended intensity or turn off the device during operation through the same control knob. While device is turned on for operation, the related LCD icons then illuminate for indicating the device is in operation condition. User then follow the instruction for use to get appropriate stimulation treatment for urinary incontinence.

With the combination of the main device parts as above mentioned , the device can be used as recommended in manual for the treatment of urinary incontinence for over-the-counter (OTC) use as that of the chosen 510(K) predicate device.

6. Intended Use:

The Everyway Incontinence Stimulation System 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.

7. Comparison to the 510(k) Cleared Device (Predicate Device):

The main reason for choosing these two predicate 510(K) clear model are because that all of them bear the same intended use as well as almost the same accessories. For the comparison concerning the device features, please see the following comparison table:

Features	510(K) Proposed Model	New Model
Model Name	Yarlap Nonimplanted electrical continence device	Everyway Incontinence Stimulation System
510(K) No.	K141643	K161349
Prescription or OTC	OTC	OTC
FDA product code	KPI	KPI
Indication 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.	The Everyway Incontinence Stimulation System 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.
Electrode Used	Incontinence probe PC Electrode area: 6.4cm^2 X2	Incontinence probe Electrode area: PR-02A: 7.65cm^2 X2 PR-03A: 7.87cm^2 X2 PR-04A: 6.25cm^2 X2 PR-14A: 9.05cm^2 X2

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In addition to the significant comparison feature, we also provided the comparison for the output characteristics as the following table :

For the operation mode, both predicate and new device provided the following six program modes:

New Device (EV-805I)

Program	Max.	Phase Duration	Rate	ON Time	OFF Time	Timer
P1	75mA	200us	12Hz	5 sec	5 sec.	15 min.
P2	75mA	250us	20Hz	8 sec.	8 sec.	20 min.
P3	75mA	200us	12Hz	5 sec.	10 sec.	15 min.
P4	75mA	200us	10Hz	6 sec.	12 sec.	20 min.
P5	75mA	250us	12Hz	5 sec.	15 sec.	15 min.
P6	75mA	200us	35Hz	6 sec.	18 sec.	20 min.

K141643 YARLAP

Program	Max.	Phase Duration	Rate	ON Time	OFF Time	Timer
P1	80mA	200us	12Hz	5 sec	5 sec.	15 min.
P2	80mA	250us	20Hz	8 sec.	8 sec.	20 min.
P3	80mA	200us	12Hz	5 sec.	10 sec.	15 min.
P4	80mA	200us	10Hz	6 sec.	12 sec.	20 min.
P5	80mA	250us	12Hz	5 sec.	15 sec.	15 min.
P6	80mA	200us	35Hz	6 sec.	18 sec.	20 min.

8. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of the devices are as the followings:

Compliance to applicable voluntary standards includes IEC 60601-2-10, as well as IEC 60601-1, IEC60601-1-11 and IEC 60601-1-2 requirement. In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

Discussion: The Compliance to applicable voluntary standards as above mentioned indicates that the new device in this submission used the same standards as that of predicate device. Therefore; we consider that the compliance of standards included in our submission is adequate for the determination of substantial equivalence.

9. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:

The Usability Study was conducted for the Everyway Incontinence Stimulation System to support the device design and labeling for over-the-counter use of the device.

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10. Summary for the technology comparison.

Basically the Everyway Incontinence Stimulation System has the similar technological characteristics with the predicate device in the product design, material, energy source type, main program mode and the main output waveform…etc. There exists some difference in the detailed output parameters (mainly in the output intensity and electrode sizes). Through the detailed calculation comparison of stimulation output energy for each operation mode(in particular the output current density and power density), we found the output level in each operation mode for our Everyway Incontinence Stimulation System and predicate device are very close and within the acceptable range. So we believe the difference in detailed output parameters does not affect the determination of substantial equivalence.

11. Conclusions

The Everyway Incontinence Stimulation System has the same intended use and the similar technological characteristics as the cleared devices. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.