DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 2, 2015

Everyway Medical Instruments Co., Ltd.
Robert Tu
3FL., No 5, Lane 155, Section 3 Peishen Rd.
Shen Keng Hsiang, Taipei Hsien
Taiwan, 222, ROC

Re: K142794
Trade/Device Name: Everyway Facial MENS, model MT-200
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO
Dated: May 1, 2015
Received: May 4, 2015

Dear Mr. 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" (21CFR 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,

Felipe Aguel -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)*
K142794

Device Name
Everyway Facial MENS, model: MT-200

Indications for Use *(Describe)*
The Everyway Facial MENS, model: MT-200 is intended for facial stimulation and indicated for over-the-counter cosmetic use.

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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EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
3Fl., No. 5, Lane 155, Sec. 3,Peishen Rd, Shen Keng Hsiang, Taipei Hsien, Taiwan,

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 June 15, 2011.

The assigned 510(k) number is: K142794 .

1. Submitter's Identifications:

   Establishment: EVERYWAY MEDICAL INSTRUMENT CO., LTD.
   Address: 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shenkeng Hsiang, Taipei Hsien 222, Taiwan
   Registration Number: 9616877
   Operations: Manufacturer

   Owner/Operator:EVERYWAY MEDICAL INSTRUMENT CO., LTD.
   Address : 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shenkeng Hsiang, Taipei Hsien 222, Taiwan
   Contact Person: Robert Tu
   Phone : 886-2-2662-0038
   Fax No: 886-2-2664-5566
   e-mail : tu922@ms35.hinet.net

2. Name of the Device:
   Everyway Facial MENS/ Model: MT-200.

3. Information of the 510(k) Cleared Device (Predicate Device):

   K072260: NuFace® Facial Toning Device.

4. Classification Information:
   Trade/Device Name: Everyway Facial MENS/ Model: MT-200.
   Regulation Number: 21 CFR 882.5890
   Classification Name: Stimulator, Nerve, Transcutaneous For Pain Relief.
   Regulatory Class: II
   Product Code: NFO

5. Device Description:
   The Everyway Facial MENS, model MT-200 is a single channel transcutaneous electrical nerve stimulator intended for facial stimulation by applying an electrical current to electrodes, which are attached on the user's skin.

   The device measures 95mm(H)x 65mm(W)x23.5mm (T). Its outer housing is made of injection molded thermoplastic resin with the output contact probes consist of chrome-plated spheres. The device is powered by a 9-Volt battery to generate microcurrent that is discharged through the two fixed smooth spherical probes.

   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, a green LED will then illuminate indicating the device is in operation condition. User then follow the instruction for use to get appropriate stimulation treatment. The two probes gently glide over the skin to deliver low-level electrical impulses to strategic location on the face as his intension.

The probes of Evweyway Facial MENS, model MT-200 are designed for optimal contact with the face. The MT-200 device continually alternates the positive and negative polarity between the two output spherical probes through the internal control circuit of the device and the pulse rate set by user. The MT-200 also allows user to adjust setting output amplitude from 0 to 400 microamp for a personalized comfort level. The MT-200 device requires the use of conductive derma gel provided together with the device. With the combination of the main device parts as above mentioned, the device can be used as recommended in manual for facial stimulation and indicated for over-the-counter cosmetic use.

6. Intended Use:

The Everyway Facial MENS, model: MT-200 is intended for facial stimulation and indicated for over-the-counter cosmetic use.

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

The following features are completely identical among the predicate device and our devices.

Features	510(K) Proposed Model	New Model
Model Name	NuFace® Facial Toning Device	Everyway Facial MENS, model MT-200
510(K) No.	K072260	K142794
Prescription or OTC	OTC	OTC
FDA product code	NFO	NFO
Indication for Use	intended for facial stimulation and indicated for over-the-counter cosmetic use.	intended for facial stimulation and indicated for over-the-counter cosmetic use.
Electrode Used	Dual contact probes consist of chrome-plated spheres with diameter 30 mm. Note: Surface is 28.3cm^2/ Per contact probe	Dual contact probes consist of stainless steel hemispheres with diameter 25mm. Note: Surface is 9.8cm^2/ Per contact probe

8. Significant output characteristics comparison table:

Parameter		Predicate Device	New Device
510(K) Number		K072260	K142794
Device Name and Model		NuFace® Facial Toning Device	MT-200 Facial MENS
Manufacturer		Carol Cole	Everyway
Power Source(s)		9 Vx1	9 Vx1
- Method of Line current Isolation		Type BF	Type BF
- Patient Leakage Current		---	---
- Normal condition (*u*A)		Under 0.1	Under 0.1
- single Fault condition (*u*A)		Under 0.5	Under 0.5
Average DC current through electrodes when device is on but no pulses are being applied (*u*A)		Not applicable	Not applicable
Number of Output Modes		1 (8~10Hz)	3 (8Hz, 9Hz, 10Hz)
Number of Output Channels:	Synchronous or Alternating?	Alternating	Alternating
	Method of Channel Isolation	Output Coil	Output Coil
Regulated Current or Regulated Voltage?		0-400uA	0-3mA (load 4kΩ)
Software/Firmware/Microprocessor control?		Yes	Yes
Automatic Overload Trip?		Yes	Yes
Automatic No-Load Trip?		Yes	Yes
Automatic Shut Off?		Yes	Yes
User Override control?		Yes	Yes
Indicator Display:	On/Off Status?	Yes	Yes
	Low Battery?	Yes	Yes
	Voltage/Current Level?	Yes	Yes
Timer Range (Minutes)		Continuous	20, 40 minutes and Continuous
Compliance with Voluntary Standards?		IEC 60601-2-10	IEC 60601-2-10
Compliance with 21 CFR 898?		Yes	Yes
Weight (g) including battery		817 g	115 g
Dimensions (mm.) [W x H x D]		63.5X177.8X25.4 mm	65X95X23.5
Housing Materials and construction		ABS	ABS

For the device output features, we also provided the comparison for the output characteristics as the following table:

Parameter		Predicate Device	New Device
Mode or Program Name		NuFace^{R} Facial Toning Device	MT-200 Facial MENS
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular
Maximum Output Voltage (volts) (+/-_20 %)		0.336V @500Ω 1.14V @2KΩ 5.68V @10KΩ	1.78V @500Ω 6.64V @2KΩ 16.2V @10KΩ
Maximum Output Current (mA) (+/-_20 %)		0.672mA @500Ω 0.57mA @2KΩ 0.568mA @10KΩ	3.56mA @500Ω 3.32mA @2KΩ 1.62mA @10KΩ
Duration of primary phase (*m*Sec)		~108mS	~99-125mS (Burst)
Pulse Duration (*m*Sec)		~54mS	~49-63mS
Frequency (Hz) [or Rate (pps)]		8~10Hz	8Hz, 9Hz, 10Hz
For multiphasic waveforms only:	Symmetrical phases?	Yes	Yes
	Phase Duration (include units), (Stage range, if applicable), (both phases, if asymmetrical)	pulsed monophasic Positive:~54mS Negative: ~54mS	pulsed monophasic Positive:~49-63mS Negative: ~49--63mS
Maximum Charge(Microcoulombs per pulse) (if zero, state method of achieving zero net charge for net charge/pulse)		2.87uC	19.64uC (8Hz/500Ω)
Maximum Phase Charge(*uC*)		25.86uC	157.12uC (8Hz/500Ω)
Maximum Current Density		0.017mA/cm^2	0.26mA/cm^2 (8Hz/500Ω)
Maximum Average Current		0.48mA	2.52mA (8Hz/500Ω)
Maximum Average Power Density		0.057mW/cm^2	1.33mW/cm^2 (8Hz/10kΩ)
Burst Mode (i.e. pulse trains)	Pulse per burst	No burst mode	8~10 pulses
	Burst per second	No burst mode	~1
	Bust duration	No burst mode	~1S
	Duty Cycle	No burst mode	0.25
On Time (Second)		Constant	Constant
Off Time(second)		Constant	None
Additional Features(specify, if applicable)		NIL	NIL

9. 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, 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.

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

    No particular Clinical Test was conducted for Everyway Facial MENS, model MT-200.

11. Summary for the technology comparison.

    Basically the Everyway Facial MENS, model MT-200 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 Facial MENS, model MT-200 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.

12. Conclusions

The Everyway Facial MENS, model MT-200 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.