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

February 3, 2017

Li-Tek Electronic Technology Corporation
% Jet Li
Regulation manager
Guangzhou LETA Testing Technology Co., Ltd
6F, No.1 TianTai Road, Science City, LuoGang District
Guangzhou, CN Guangdong

Re: K162106
Trade/Device Name: Micro-current Wrinkle Reduction Facial Service, Model EP-400
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: December 31, 2016
Received: January 9, 2017

Dear Jet Li:

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)*
K162106

Device Name
Micro-current Wrinkle Reduction Facial service, Model EP-400

Indications for Use *(Describe)*
The device is intended for facial stimulation by electrode heads for cosmetic use. The device is also intended for the treatment of periorbital wrinkles with red Light Emitting Diode (LED) head. It is for over-the-counter 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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510(k) Summary
K162106

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

510k preparation date: 2017-01-25

1. Submitter's Information

510(k) Owner's Name: Li-Tek Electronics Technologies
Establishment Registration Number:
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Application Correspondent:

Company: Guangzhou LETA Testing Technology Co., Ltd.
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Science City, LuoGang District, GuangZhou City, China
Contact Person: Mr. Jet Li
Tile: Regulation Manager
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2. Subject Device Information

Type of 510(k) submission: Traditional

Common Name: Laser surgical instrument for use in general and plastic surgery and in dermatology, Transcutaneous electrical nerve stimulator for pain relief.

Trade Name: Micro-current Wrinkle Reduction Facial service, model EP-400

Classification Name: Light Based Over The Counter Wrinkle Reduction; Stimulator,

Transcutaneous Electrical, Aesthetic Purposes

Review Panel: General & Plastic Surgery, Neurology

Product Code: OHS, NFO

Regulation Number: 878.4810, 882.5890

Regulation Class: 2

3. Predicate Device Information

Sponsor	Biosonic Technologies, LIC.	EVERYWAY MEDICAL INSTRUMENT CO., LTD.	Carol Cole Company	Nutra Luxe MD, LLC
Device Name	Beautiful Image Model 900 Facial Toning Device	MT-200 Facial MENS	NOFACE® Plus	Nutra Light Red
510(k) Number	K130045	K142794	K103472	K141308
Product Code	NFO	NFO	NFO	OHS
Regulation Number	882.5890	882.5890	882.5890	878.4810
Regulation Class	2	2	2	2

4. Device Description

The Device is equipped with three replaceable treatment heads; two treatment heads are electrode heads for micro current output to stimulate facial skin (Bigger one, and smaller one), the other treatment head is LED lamp holder.

The device is intended for facial stimulation by electrode heads for cosmetic use. The device is also intended for the treatment of periorbital wrinkles with red Light Emitting Diode (LED) head. It is for over-the-counter use.

For two micro current treatment heads of instrument, they can be exchanged for different skin part to use. The bigger one is for face tissue on cheeks and the smaller one is for facial tissue below eye region. It should be used about 10 minutes/2 to 3 times per week. The red light head is for red-light caring (about 3 minutes/2 to 3 times per week.)The product is supplied with an internal lithium rechargeable battery; It can be charged by 5V voltage of battery charger connected by standard USB cable. During battery charging, the LED lights start flash circling until charging is completed.

There are two kinds of electrode heads, one bigger electrode head is for cheek stimulation; and smaller electrode head is for stimulation on under eyes area. There are no electronic component inside of either heads. It is only for conduct stimulation current.

5. Intended Use / Indications for Use

The device is intended for facial stimulation by electrode heads for cosmetic use. The device is also intended for the treatment of periorbital wrinkles with red Light Emitting Diode (LED) head. It is for over-the-counter use.

6. Test Summary

EP-400 has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Photobiological safety of lamps and lamp systems according to IEC62471
- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"
- Waveform test report to verify the output specifications of the device according to IEC 60601-2-10 and Guidance for Powered Muscle Stimulator.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of EP-400 is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety and effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Predicate Device**	**Predicate Device**	**Predicate Device**	**Remark**
Basic Unit Characteristics						
Device Name and Model	Micro-current Wrinkle Reduction Facial Service, model EP-400	Beautiful Image Model 900 Facial Toning Device	MT-200 Facial MENS	NOFACE® Plus	Nutra Light Red	--
510 (K) Number	K162106	K130045	K142794	K103472	K141308	--
Product Code	NFO，OHS	NFO	NFO	NFO	OHS	--
Regulation Number	882.5890 878.4810	882.5890	882.5890	882.5890	878.4810	--

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
Intended Use	The device is intended for facial stimulation by electrode heads for cosmetic use. The device is also intended for the treatment of periorbital wrinkles with red Light Emitting Diode (LED) head. It is for over-the-counter use.	Biosonic Technologies Model 900 Facial Toning Device is intended for facial stimulation and is indicated for prescription cosmetic use. The anatomical site for application of the Model 900 is the face.	The Everyway Facial MENS, model: MT-200 is intended for facial stimulation and indicated for over-the-counter cosmetic use.	The NOFACE® Plus Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use. (21 CFR 801 Subpart C). The anatomical site for application of the NOFACE® Plus is the face.	The Nutra Light Red is a non-invasive LED light device is intended/indicated for over- the – counter use for the treatment of periorbital wrinkles, and rhytides.	SE Note 1
Apply parts	For micro current stimulation: Face; For Red light: periorbital	Face	Face	Face	periorbital	SE
Power Sources	1200mAh lithium battery	One 6V battery	9-Volt battery	4 rechargeable batteries	Internal NI-MH rechargeable battery	SE Note 1
Method of Line Current Isolation	Battery Supply N/A	N/A	Type BF	N/A	N/A	SE Note 1
For Micro current facial stimulation function						
Number of Modes for Micro current stimulation	1	1	3 (8Hz, 9Hz, 10Hz)	1	N/A	SE Note 1
Number of Channels for Micro current stimulation	1	1	1	1	N/A	SE

Elements of Comparison		Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
-Synchronous or Alternating		Alternating	N/A	Alternating	Alternating	N/A	SE Note 1
Regulated Current or Regulated Voltage		Regulated Voltage	Both	0-3mA (load 4kΩ)	Regulated Voltage	N/A	SE Note 1
Software/Firmware/Microprocessor control		Yes	Yes	Yes	Yes	Yes	SE
Automatic Overload Trip		Yes	Yes	Yes	Not required due to circuit design	N/A	SE
Automatic No-load Trip		Yes.	Yes	Yes	Yes	N/A	SE
Automatic Shut Off		Yes.	Yes	Yes	Yes	N/A	SE
Patient Override Control		Yes	Yes	N/A	Yes	N/A	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	Yes	N/A	SE
	Low Battery	Yes	Yes	Yes	Yes	N/A	SE
	Voltage/Current Level	Yes	Yes	Yes	Yes	N/A	SE
Timer Range		10 minutes	None	20, 40 minutes and Continuous	21 minutes	N/A	SE Note 1
Housing Materials and Construction		Console: ABS plastic	Thermoplastic	ABS	Thermo Plastic	medical grade biocompatibility plastics via injection molding	SE Note 1
Output Specification							

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
Waveform	Pulsed Biphasic	Biphasic	Biphasic	Pulsed Monoilhasic	N/A	SE Note 2
Shape	Rectangular	Rectangular	Rectangular	Modulated Square	N/A	SE Note 2
Maximum Output Voltage (+/- 10%)	1.23V @ 500Ω 3.64V @ 2kΩ 10.9V @ 10kΩ	0.347V @ 500Ω 1.242V @ 2kΩ 5.780V @ 10kΩ	1.78V @500Ω 6.64V @2KΩ 16.2V @10KΩ	137mV @ 500Ω 769mV @ 2kΩ 3.82V @ 10kΩ	N/A	SE Note 2
Maximum Current Density	2.46mA @ 500Ω 1.82mA @ 2kΩ 1.09mA @ 10kΩ	0.647mA @ 500Ω 0.625mA@ 2kΩ 0.584mA@ 10kΩ	3.56mA @500Ω 3.32mA @2KΩ 1.62mA @10KΩ	274μA @ 500Ω 387μA @ 2kΩ 382μA @ 10kΩ	N/A	SE Note 2
Frequency range	59.3Hz	0.62 1 - 308.6Hz	8Hz, 9Hz, 10Hz	8.40 Hz	N/A	SE Note 2
Pulse width range	4ms	3.24-1610ms	N/A	119ms	N/A	SE Note 2
Pulse duration	4ms	3.24-1610ms	~49-63ms	N/A	N/A	SE Note 2
Net Charge	9.04μC@ 500Ω	0 uC @5000	N/A	N/A	N/A	SE Note 2
Maximum Phase Charge	16.4μC@ 500Ω	190μC@ 500Ω	157.12uC (8Hz/500Ω)	23.06μC@ 500Ω	N/A	SE Note 2
Maximum Current Density	Bigger electrode head: 0.044 mA/cm²@ 500Ω Smaller electrode head: 0.42 mA/cm²@ 500Ω	1.486mA/cm²@ 500Ω	0.26mA/cm^2 (8Hz/500Ω)	0.419 mA/cm²@ 500Ω	N/A	SE Note 2
Maximum Power Density	Bigger electrode head 0.014 mW/ cm²@ 500Ω Smaller electrode head 0.139 mW/ cm²@ 500Ω	366 μW/cm² @ 500Ω	1.33mW/cm^2 (8Hz/10kΩ)	3.22 μW/cm² @ 500Ω	- N/A	SE Note 2
ON time	Constant	10-30s	Constant	Constant	N/A	SE
OFF time	None	1-6s	None	None	N/A	SE

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
Contraction and Relaxation time	Adjustable, due to different modes.	Adjustable, due to different modes.	--	--	N/A	SE
For LED red light irradiation function						
LED wavelength	650+/-5nm	--	--	--	650 +/- 5nm	SE
LED Power Density	80mW/cm^2	--	--	--	80mW/cm^2	SE
Additional Features						
Environment for operating	Temperature: 5 ~ 40° C	+ 50 to 1040 F (+10 to +40° C)	--	--	--	SE
Environment for storage	Temperature: -25 ~70° C Humidity: 10 ~90% RH	- 29 to + 1670 F (-34 to +76° C) 0 to 95% - non-condensing	--	--	--	SE
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 and IEC 62471:2006 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 , ISO10993-10 and IEC 62471:2006 requirements.	SE
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

Although the Power Sources, Method of Line Current Isolation, Synchronous or Alternating, Regulated Current or Regulated Voltage, Timer Range, Console weight, Housing Materials and

Construction are a little different from the predicate devices, they are all compliant with requirements of IEC 60601-1, IEC 60601-1-2 and Guidance for Powered Muscle Stimulator. So the differences of the function specifications do not raise any safety or effectiveness issue.

Note 2:

Although the Waveform, Shape, maximum output voltage, maximum current density, frequency range, pulse width range, pulse duration, net charge, maximum phase charge, maximum current density, maximum power density, on time, off time, contraction and relaxation time of subject device are a little different from the predicate devices, they are all compliant with the requirements of IEC 60601-1, IEC 60601-2-10, and Guidance for Powered Muscle Stimulator. So the differences of function specification do not raise any safety or effectiveness issue.

Conclusion:

The subject device "Micro-current Wrinkle Reduction Facial Service, model EP-400" is Substantial Equivalence to the predicate devices.