DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 25, 2017

Li-tek Electronic Technology Corporation
% Mr. Jet Li
Regulation Manager
Guangzhou Leta Testing Technology Co., Ltd
6f, No.1 Tiantai Road, Science City, Luogang District
Guangzhou, China

Re: K162652
Trade/Device Name: Smart Photon Micro-current Device: EP-300
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO, OHS, OLP
Dated: September 14, 2017
Received: September 19, 2017

Dear Mr. 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,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K162652

Device Name
Smart Photon Micro-current Device, Model: EP-300

Indications for Use *(Describe)*
For micro current stimulation mode: The Smart Photon Micro-current Device is intended for facial stimulation and is indicated for over-the-counter aesthetic use.
For red light irradiation mode: The red light is intended for the treatment of periorbital wrinkles,
For blue light irradiation mode: The blue light is for the treatment of mild to moderate acne.

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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Chapter 6.510(k) Summary

510(k) Summary

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

1. Date of the summary prepared: October 25, 2017

There is no prior submission for the device.

2. Submitter's Information

510(k) Owner's Name: Li-Tek Electronic Technology Corporation

Establishment Registration Number:

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Contact Person: Barry Yuan (Quality Director)

E-mail: quality5@li-tek.com

Application Correspondent:

Company: Guangzhou LETA Testing Technology Co., Ltd.

Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhouCity, China

Contact Person: Mr. Jet Li

Tile: Regulation Manager

Tel: +86-20-22325619

Email: med-jl@foxmail.com

3. Subject Device Information

Type of 510(k) submission: Traditional

Common Name: Light based over the counter wrinkle reduction；over-the-counter powered light based laser for acne；stimulator, transcutaneous electrical, aesthetic purposes.

Trade Name: Smart Photon Micro-current Device, Model: EP-300

Classification Name: Light Based Over the Counter Wrinkle Reduction; Stimulator, Transcutaneous Electrical, Aesthetic Purposes; Over-the-counter powered light based laser for acne.

Review Panel: General & Plastic Surgery, Neurology

Product Code: OHS, NFO, OLP

Regulation Number: 878.4810, 882.5890

Regulation Class: 2

4. Predicate Device Information

Sponsor	Biosonic Technologies, LIC.	EVERYWAY MEDICAL INSTRUMENT CO., LTD.	Home Skinovations Ltd.	Nutra Luxe MD, LLC
Device Name	Beautiful Image Model 900 Facial Toning Device	MT-200 Facial MENS	Silkn Blue	Nutra Light Red
510(k) Number	K130065	K142794	K121435	K141308
Product Code	NFO	NFO	OLP	OHS
Regulation Number	882.5890	882.5890	882.5890	878.4810
Regulation Class	2	2	2	2

2. Device Description

There are Micro current electrodes, Red LEDs, Blue LEDs in the treatment head for their individual treatment function. The device is provided with three operating function modes: Micro current stimulation mode, Red light irradiation mode, Blue light irradiation mode. Three operation modes can be selected by the “Mode” button. These modes only can work separately.

For Micro current stimulation mode:

The device has two pairs of electrode contactors for facial stimulation by applying an electrical micro current to electrodes. The output waveform is formed of regulated Voltage of Biphasic pulse and provided with 5 levels of output intensity, which can be adjusted by user.

The device requires the use of conductive gel provided together with the device.

For LED phototherapy function:

The device also can provide specific photon spectrum by LED lamps for Red light irradiation mode and Blue light irradiation mode. There are Red LED lamps and Blue LED lamps assembled in the treatment head.

In Red light irradiation mode, the device utilizes Light Emitting Diodes to emit red light. The output is pre-tuned to one wavelength with a narrow spectral bandwidth. The output wavelength of red light is 630±10nm and its power density is 80 mW/cm^2.

In Blue light irradiation mode, the device utilizes Light Emitting Diodes to emit blue light. The output is pre-tuned to one wavelength with a narrow spectral bandwidth. The output wavelength of blue light is 415 ±10 nm and its power density is about 50 mW/cm^2.

For the facial stimulation model, the recommend treatment session is 10 minutes/2 to 3 times per week.

For light irradiation of red light, the recommend treatment session is 3 minutes/ 2-3 times per week. And for blue light, the recommend treatment session is 4 minutes/ 2 times per week on each treatment area.

5. Intended Use / Indications for Use

For micro current stimulation mode: The Smart Photon Micro-current Device is intended for facial stimulation and is indicated for over-the-counter aesthetic use.

For red light irradiation mode: The red light is intended for the treatment of periorbital wrinkles,

For blue light irradiation mode: The blue light is for the treatment of mild to moderate acne.

6. Test Summary

EP-300 has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1:2005 +A1:2012 and IEC 60601-2-10: 2012 standards
- Electromagnetic compatibility test according to standard IEC 60601-1-2: 2014
- Photo biological safety of LED lamp systems according to IEC62471:2006
- 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 60601-2-10:2012 and Guidance for Powered Muscle Stimulator.
- Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use according to IEC60601-2-57:2011

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of EP-300 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 or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Predicate Device**	**Predicate Device**	**Predicate Device**	**Remark**
Basic Unit Characteristics						
Device Name and	Smart Photon Micro-current	Beautiful Image Model 900	MT-200 Facial	Silkn Blue	Nutra Light Red	--

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
Model	Device, Model: EP-300	Facial Toning Device	MENS			
510 (K) Number	Applying	K130065	K142794	K121435	K141308	--
Product Code	NFO，OHS，OLP	NFO	NFO	OLP	OHS	--
Regulation Number	882.5890，878.4810	882.5890	882.5890	878.4810	878.4810	--
Intended Use	For micro current stimulation mode: The device is intended for facial stimulation and is indicated for over-the-counter aesthetic use. For red light irradiation mode: The red light is intended for the treatment of periorbital wrinkles,	Biosonic Technologies Model 900 Facial Toning Device is intended for facial stimulation and is indicated for prescription aesthetic 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 aesthetic use.	The Silkn Blue is indicated as an over the counter phototherapy device for the treatment of mild to moderate acne	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

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
	For blue light irradiation mode: The blue light is for the treatment of mild to moderate acne.					
Apply parts	Face	Face	Face	Face	Face	SE
Power Sources	3.7V, 800mAh rechargeable lithium battery	One 6V battery	9-Volt battery	batteries	4 rechargeable batteries	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)	N/A	N/A	SE
Number of Channels for Micro current stimulation	1	1	1	N/A	N/A	SE
-Synchronous or Alternating	Alternating	N/A	Alternating	--	N/A	SE
Regulated Current or Regulated Voltage	Regulated Voltage	Both	0-3mA (load 4kΩ)	Regulated Voltage	N/A	SE
Software/Firmware/Micropro	Yes	Yes	Yes	Yes	Yes	SE

Elements of Comparison		Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
cessor control							
Automatic Overload Trip		Yes	Yes	Yes	--	N/A	SE
Automatic No-load Trip		Yes.	Yes	Yes	--	N/A	SE
Automatic Shut Off		Yes.	Yes	Yes	--	N/A	SE
Patient Override Control		Yes	Yes	--	--	N/A	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	--	--	SE
	Low Battery	Yes	Yes	Yes	--	--	SE
	Voltage/Current Level	Yes	Yes	Yes	--	--	SE
Timer Range		Yes(10 minutes)	None	20, 40 minutes and Continuous	--	--	SE Note 2
Console weight		125 g including battery	10lbs	115 g including battery	--	--	SE Note 3
Housing Materials and Construction		Console: ABS plastic	Thermoplastic	ABS	Stainless steels 17-4H, Rigid ABS	medical grade biocompatibility plastics via injection	SE

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
					molding	
Micro current Output Specification						
Waveform	Pulsed Biphasic	Biphasic	Biphasic	N/A	N/A	SE
Shape	Rectangular	Rectangular	Rectangular	N/A	N/A	SE
Maximum Output Voltage (+/- 10%)	1.49V @ 500Ω 2.48V @ 2kΩ 10.6V @ 10kΩ	0.347V @ 500Ω 1.242V @ 2kΩ 5.780V @ 10kΩ	1.78V @500Ω 6.64V @2KΩ 16.2V @10KΩ	N/A	N/A	SE Note 4
Maximum output Current	2.98mA @ 500Ω 1.24mA @ 2kΩ 1.06mA @ 10kΩ	0.647mA @ 500Ω 0.625mA@ 2kΩ 0.584mA@ 10kΩ	3.56mA @500Ω 3.32mA @2KΩ 1.62mA @10KΩ	N/A	N/A	SE Note 4
Frequency range	60Hz	0.62 1 - 308.6	8Hz, 9Hz, 10Hz	N/A	N/A	SE Note 5
Pulse width range	4ms	3.24-1610 ms	--	N/A	N/A	SE Note 5
Pulse duration	4ms	3.24-1610 ms	~49-63mS	N/A	N/A	SE Note 5
Net Charge	0 µC @ 500Ω	0 uC @500Ω	19.64 uC	N/A	N/A	SE
Maximum	0.524mA/cm²@	1.486mA/cm²@	0.26mA/cm2	N/A	N/A	SE

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
Current Density	500Ω	500Ω	(8Hz/500Ω)			Note 6
Maximum Power Density	0.216mW/cm²@ 500Ω	0.366 mW/cm² @ 500Ω	1.33mW/cm2 (8Hz/10kΩ)	N/A	N/A	SE Note 6
ON time	Constant	10-30s	Constant	N/A	N/A	SE
OFF time	None	1-6s	None	N/A	N/A	SE
Contraction and Relaxation time	Adjustable, due to different modes.	Adjustable, due to different modes.	--	N/A	N/A	SE
For LED red light irradiation function						
LED wavelength	Red-light: 630±10nm Blue light :415±10nm	--	--	415±15nm	650 +/- 5nm	SE Note 7
LED Power Density	Red light: 80 W/cm2 Blue light: 50 W/cm^2	--	--	50 W/cm^2	80mW/cm^2	SE
Additional Features						
Environment	Temperature: 5	+ 50 to 104° F				SE

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Remark
for operating	~ 40° C Relative humidity: <93% RH	(+10 to +40° C)	--	--	--	
Environment for storage	Temperature: -25° C ~ 50° C Relative humidity: 10~95% RH	- 29 to + 167° F (-34 to +76° C) 0 to 95% - non-condensing	--	--	--	SE
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 ,ISO 10993-10 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 62471:2006requirements.	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	Comply with IEC 60601-1	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 (Power Source(s) and Method of Line Current Isolation):

The design of the power source is according to the circuit design of the device, which should ensure the safety and effectiveness. Our product complies with IEC 60601-1 requirements, so the difference on Power source and method of line current isolation would not introduce electric

safety impact. Also, the performance of our device is substantially equivalent to the predicate devices under this power supply condition, which would be discussed in the follow description.

Note 2 (Timer Range):

The design of the timer range is basing on the intended use. As the subject device has three functions, including Red LED light therapy, Blue LED light therapy and Micro current stimulation, therefore the user could adjust the time by the modes based on user instruction. And the user will adjust the time as recommended treatment time for expected result according to the user manual. So the difference of timer range would not affect the safety and effectiveness of subject device.

Note 3 (Weight):

Even the weight of device is different to the predicate device, but all of them belong to handled device, and it complied with IEC60601-1 Testing. So the minor difference on weight and dimensions won't affect the safety and effectiveness of the device so it can deemed as the substantially equivalence.

Note 4 (Maximum Output Voltage and Maximum Output Current):

The effect of micro current stimulation are determined by micro current output waveform and output current. There is minor difference on the maximum output voltage and current between the subject device and the predicate devices, however the value of output voltage and output current are in the range which is between the value of K130065 and K142794. Also, the subject device complies with IEC 60601-1 and IEC60601-2-10 for safety and performance evaluation. Therefore, the difference on maximum output voltage and output current would not affect the safety and effectiveness of subject device.

Note 5 (Frequency and Pulse duration):

The effect of micro current stimulation are determined by micro current output waveform and output current. Frequency and pulse duration is the time parameter of the waveform. There is only little difference on the Frequency and pulse duration between the subject device and the predicate devices, it can still obtain the same effect because our output voltage and output current is in the range which is between the value of K130065 and K142794, and the Frequency,

Pulse duration was cover by K130065. Also, the subject device complies with IEC 60601-1 and IEC60601-2-10 for safety and performance evaluation. Therefore, the difference on Frequency and Pulse duration would not affect the safety and effectiveness of subject device.

Note 6 (Maximum current density and Maximum power density):

The effect of micro current stimulation on facial skin are determined by micro current output waveform and output current. There is minor difference on the maximum current density and maximum power density between the subject device and the predicate devices, but the value of current density and maximum power density of subject device are in the range which is between the value of K130065 and K142794. And the maximum power density meet with the maximum allowed value 0.25 (W/cm^2) required in FDA guidance. Therefore, the subject device and predicate devices are substantially equivalence on these parameters.

Note 7 (LED Wavelengths):

The wavelength of blue light of subject device is same to predicate device and the red light is very close to the predicate device. The difference of the red light wavelength is minor between the subject device and the predicate devices; and the subject device has passed the testing according to IEC62471 and IEC60601-2-57 for safety and performance evaluation. Therefore, we thought that such difference on the wavelengths of LED light would not affect the safety and effectiveness of subject device.

Finial Conclusion:

The subject device Smart Photon Micro-current Device, Model: EP-300 is Substantial Equivalence to the predicate devices.