DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 30, 2017

Li-Tek Electronic Technology Corporation
% Jet Li
Regulation Manager
Guangzhou Leta Testing Technology Co.,Ltd
6F, No.1 Tian Tairoad Science City, LuoGang District
Guang Zhou City, China

Re: K162098
Trade/Device Name: LED Phototherapy Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: OLP and OHS
Dated: December 31, 2016
Received: January 10, 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 and Part 809), 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 -S

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

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.

510k preparation date: 2017-01-25

1. Submitter's Information

Sponsor:

- Company Name: Li-Tek Electronics Technologies
- Address: No.8~13,the industrial park of Jinshagang, Shixia village, Dalang town,Dongguan city, Guangdong, China
- Phone: 0769-83117755
- Fax: 0769-83117759
- Contact Person (including title): Barry Yuan (Quality Director)
- E-mail:quality5@li-tek.com

Application Correspondent:

- Guangzhou LETA Testing Technology Co., Ltd.
- Address: 6F, No.1 TianTairoad, Science City, LuoGang District, GuangZhou City, China
- Contact Person: Mr. Jet Li
- Tile: Regulation Manager
- Tel: +86-20-22325619
- Email: med-jl@foxmail.com

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.

Light Therapy system

Trade Name: LED Phototherapy Device

Classification Name: Light Based over the Counter Wrinkle Reduction, Over-the-counter powered light based for acne

Review Panel: General&Plastic Surgery

Product Code: OLP, OHS

Regulation Number: 878.4810

Regulation Class: 2

3. Predicate Device Information

Sponsor	Home Skinovations Ltd.	Silver Bay, LLC	NutraLuxe MD, LLC
Device Name	Acne Treatment device	Quasar Calypso	Nutra Light Red
510(k) Number	K121435	K111286	K141308
Product Code	OLP	OLP	OHS
Regulation Number	878.4810	878.4810 and 890.5500	878.4810
Regulation Class	2	2	2

4. Device Description

The LED Phototherapy Device (Model: PL-120) directly applies photon light onto skin surface by making using of specific photon spectrum. Each device is equipped with two LED lamp holder, one is emitting blue light which wavelength at 415nm±3nm. The other lamp emits red light which wavelength at 630nm±3nm. The red light is intended for the treatment of periorbital wrinkles. The blue light is intended for the treatment of the mild to moderate inflammatory acne. The user can change the treatment lamp according to their own needs. It employed a 3.7 V Li-ion battery to provide power, and the internal battery is rechargeable. And the device has five options for setting the auto-off time, as below table listed:

Mode Selection	Default Duration
1	Auto Off after running for 1 minute
2	Auto Off after running for 2 minute
3	Auto Off after running for 3 minute
4	Auto Off after running for 4 minute
L	Continuous working mode

5. Intended Use / Indications for Use

The red light is intended for the treatment of periorbital wrinkles, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.

6. Materials

There are no patient directly contracting components in the subject device as the following list.

Component of Device Requiring Biocompatibility	**Material of Component**	**Body Contact Category (ISO 10993-1)**	**Contact Duration (ISO 10993-1)**
-	-	-	-

The holding part is made of ABS plastic, which is widely used in various medical devices, and its biological compatibility has been proved to be acceptable in many marketed device. So biological compatility test was waived here for this material. The users should place the device 2-3cm away from face before use it. So the LED Phototherapy device is not used in skin contact.

7. Physical characteristics

Main Unit Weight		150g
dimensions（L*W*H）		187*65*51mm
Power Source		DC 5V，1A
Maximum power		1.5W
light source		LED
Maximum emission wavelength		The red light：630nm±3nm
		The blue light：415nm±3nm
Power density		The red light：80mW/cm^2±10%
		The blue light：65mW/cm^2±10%
Irradiation area		30cm²±5%
The distance between the lamp to treatment skin surface		2-3cm
Li battery		3.7V，1050mAh
Maximum charging time		3 hours
work environment	Temperature	5℃-40℃
	relative humidity	10%-80%
	atmospheric pressure	700hPa~1060hPa
Transportation and storage conditions	Temperature	-10℃-40℃
	relative humidity	5%-95%
	atmospheric pressure	600hPa~1060hPa

8. Test Summary

The LED Phototherapy Device has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety and essential performance test according to IEC 60601-1; IEC 60601-2-57 IEC60601-1-11 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Photobiological safety test 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 Device"

9. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of the LED Phototherapy Device is substantially equivalent to the predicate device quoted above.

The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**			**Remark**
Device Name and Model	LED Phototherapy Device. Model:PL-120	Silkn Blue	Quasar Calypso	Nutra Light Red	--
510(k) Number	Applying	K121435	K111286	K141308	--
Manufacturer	Li-Tek Electronics Technologies	Home Skinovations Ltd	PhotoActif, LLC	NutraLuxe MD, LLC	--
Product Code	OLP	OLP	OLP	OHS	--
Regulation Number	878.4810	878.4810	878.4810 and 890.5500	878.4810	--
Intended Use	The red light is intended for the treatment of periorbital wrinkles, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	The Silkn Blue is indicated as an over the counter phototherapy device for the treatment of mild to moderate acne.	The Quasar Calypso C5O is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne vulgaris.	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
Basic Unit Characteristics					
Power Source(s)	3.7V 1050mAh Li battery	battery	12 volt wall mount power	internal NI-MH rechargeable battery	SE Note 1
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	No	SE Note1

Elements of Comparison	Subject Device	Predicate Device			Remark
Power (mW/cm^2)	Red light 80±10% Bule light 65±10%	50	65	80	SE Note 1
treatment duration	3 minutes per target area; 2 treatments per week for 6 weeks	--;	3 minutes daily, minimum 5 days per week	3min	SE
Compliance with 21 CFR 898	Yes	Yes	Yes	Yes	SE
Housing Materials and Construction	ABS plastic	Stainless steels 17-4H, Rigid ABS	polycarbonate	medical grade biocompatibility plastics via injection molding	SE
wavelength	blue light：415nm±3nm red light：630nm±3nm	415±15nm	Blue light 405-420nm,red light 628±10nm	The output wavelength of Red is 650 +/- 5 at 80 mW/cm2	SE Note 2
Standards					
Biocompatibility	ABS plastic in hand hold part can be considered safety	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.	SE
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Comply with IEC / EN 6060 1-1	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	SE

Comparison in Detail(s):

Note 1:

“Power Source(s)”“Power (mW/cm)”is belonging to basic characteristics. Although they are a little different from the predicate device, it will not affect the main function and the intended use of the device. They all also comply with IEC 60601-1, IEC 60601-1-2, IEC62471, for safety requirement, and comply with IEC60601-2-57 for essential requirements. So the differences will not raise any safety or effectiveness issue.

Note 2: "wavelength" of subject device is a little different from the predicate device, they all comply with IEC62471, IEC60601-2-57requirement, so the differences of function specification will not raise any safety or effectiveness issue.

Finial Conclusion:

The subject device LED Phototherapy Device is substantial equivalence to all predicate devices.

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)*
K162098

Device Name
LED Phototherapy Device

Indications for Use *(Describe)*
The red light is intended for the treatment of periorbital wrinkles, and the blue light is intended for the treatment of the mild to moderate inflammatory 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.