DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 28, 2017

Li-Tek Electronics Technologies
c/o Shiling Li
Guangzhou KunSBo Managing Consultancy Co., Ltd
Building H, No 199 Kezhu Road,
Guangzhou Science City
Guangzhou, Guangdong Province, China 510000

Re: K161434
Trade/Device Name: Photon Vibrating massage Facial Aesthetic Device (Model: UI-200)
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
Dated: August 23, 2017
Received: September 1, 2017

Dear Shiling 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" (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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K161434

Device Name
Photon Vibrating Massage Facial Aesthetic Device , Model: UI-200

Indications for Use *(Describe)*
The Photon Vibrating massage Facial Aesthetic Device (Model: UI-200) is intended for over-the-counter use.
LED functional mode
- To emit energy in the blue and red region of the spectrum, specifically to treat mild to moderate acne on the face.
- To emit energy in the blue region of the spectrum to treat mild to moderate inflammatory acne.

Vibrating massage functional mode
As an electrically powered device intended for medical purposes to relieve minor aches and pains.

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

Date of the summary prepared: September 28, 2017

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

1. Submitter's Information

- 510(k) Owner's Name: Li-Tek Electronics Technology Corporation
- Establishment registration number: Applying
- Address: No. 8~13, Industrial Park of Jinshagang, Shixia village, Dalang town, Dongguan city, Guangdong, China
- Phone: 0769-83117755
- Fax: 0769-83117754
- Contact Person (including title): Barry Yuan (Quality Director)
- E-mail: quality5@li-tek.com

2. Application Correspondent

- Contact person: Mr. Jet Li
- Company name: Guangzhou KunSBo Managing Consultancy Co., Ltd
- Tel: +86-18588874857
- Email: med-jl@foxmail.com

3. Subject Device Information

♦ Trade Name:	Photon Vibrating massage Facial Aesthetic Device, Model: UI-200
♦ Common Name:	Acne Light Therapy System
♦ Classification name:	Over-the-counter powered light based laser for acne; Therapeutic massager
♦ Review Panel:	General & Plastic Surgery, Physical Medicine

- Product Code: OLP, ISA
- Regulation Class: 2
- Regulation Number: 878.4810, 890.5660

a) Predicate Device Information

Sponsor	Accord Media	Syneron Beauty Inc.	NutraLuxe MD, LLC
Device Name	Ultra Renew Plus	Tanda Mini Skincare System	Pulsaderm Acne Device
510(k) Number	K132833	K124042	K161941
Product Code	OLP, OHS, ISA	OLP	OLP
Regulation Number	878.4810, 890.5660	878.4810	878.4810
Regulation Class	2	2	2

4. Device Description

Photon Vibrating massage Facial Aesthetic Device, Model: UI-200 is a device provided with two operation functions: Vibrating massage and LED light irradiation. The product provided with internal battery and it can be charged by external adaptor.

For LED light irradiation functional, the device provides with two LED irradiation modes: Blue Light working Mode, Blue and Red Light working Mode, which can be switched by Mode button. When the device works in red and blue light working mode, the device provides spectral emission with LED red light (630±10nm) and blue light (415±10nm). In blue light working mode, the device only provide LED blue light output (415±10nm) by the LED lamp module in treatment head.

When the device works in Vibrating massage mode, the vibration can be provided on the stainless steel contactor in treatment head and can provide vibrating massage to facial skin.

5. Intended Use / Indications for Use

The Photon Vibrating massage Facial Aesthetic Device (Model: UI-200) is intended for over-the-counter use.

LED functional mode

- To emit energy in the blue and red region of the spectrum, specifically to treat mild to moderate acne on the face.
- To emit energy in the blue region of the spectrum to treat mild to moderate inflammatory acne.

Vibrating massage functional mode

As an electrically powered device intended for medical purposes to relieve minor aches and pains.

6. Design

Photon Vibrating massage Facial Aesthetic Device, Model: UI-200 is a device provided with two operation functions: Vibrating massage and LED light irradiation. The product provided with internal battery and it can be charged by external adaptor.

For LED light irradiation functional, the device provides with two LED irradiation modes: Blue Light working Mode, Blue and Red Light working Mode, which can be switched by Mode button. When the device works in red and blue light working mode, the device provides spectral output with LED red light (630±10nm) and blue light (415±10nm). In blue light working mode, the device only provide LED blue light output (415±10nm) by the LED lamp module in treatment head.

When the device works in Vibrating massage mode, the vibration can be provided on the stainless steel contactor in treatment head and can provide vibrating massage to facial skin.

For aforementioned three operation modes, they can only operate separately.

7. Materials

There is one of patient directly contracting component in the subject device as the following list.

Component of	Material of	Body Contact	Contact Duration

Device Requiring Biocompatibility	Component	Category (ISO 10993-1)	(ISO 10993-1)
stainless steel treatment head for vibrating massage	Stainless steel	Surface-contacting device: skin	Maximum 2 hours (< 24hours)

The Nature of body contact is surface-skin contact. And the contact duration is less than 24 hours. According to Table 1 - Initial evaluation tests for consideration in ISO 10993-1, the applicable biological effect is:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity

8. Physical characteristics

Table I

Basic Unit Characteristics	
Method of Line Current Isolation	Type BF Applied Part
Compliance* with 21 CFR 898	Yes
Main Unit Weight	180g
Main Unit Dimension	3.7" L x 7.6" W x 2.8" D
Housing Materials of main unit	Housing made from ABS plastic and output contacts made from stainless steel.
Indicator	Indicates low battery, working mode information, intensity level for vibrating massage mode.
Time Range (minutes)	1-20 mins
Environment for operation	Temperature: 5°C~40°C Humidity: ≤ 80%
Compliance with Voluntary Standards	Yes Comply with IEC 60601-1, IEC 60601-2-57, IEC 60601-1-2
Patient leakage current	Comply with IEC 60601-1
Power Source	3.7V 1000mAh Li battery
Software/Firmware/Microprocessor Control?	Yes
Environment for Operating	Temperature: 5 ~ 40°C

	Humidity: ≤ 80%
Environment for Storage	Temperature: 0 ~ 45°C Humidity: ≤ 93% RH
Biocompatibility	Compliance with ISO10993-5 and ISO10993-10 requirements.
Electrical Safety	Comply with IEC 60601-1, and IEC60601-2-57
EMC	Comply with IEC 60601-1-2

1) For Vibrating massage Mode:

Table II

Vibration intensity level on output contactor	Level 1	Level 2	Level 3	Level 4	Level 5
Frequency for ultrasonic wave	2.98MHz	2.96MHz	2.97MHz	2.97MHz	2.97MHz
Vibrator massage pulse	84 us	105 us	124 us	144 us	164 us
Vibrator massage frequency	196.3 Hz	195.5 Hz	194.7Hz	193.9 Hz	193.2 Hz
Output Power	0.16W				

2) For LED light mode: Blue mode and Red Mode

Table III

LED Wavelengths	Red: 630±10nm, Blue: 415±10nm
LED power density	Blue: 22 mW/cm^2 Red: 7.5 mW/cm^2

10. Test Summary

Photon Vibrating massage Facial Aesthetic Device, Model: UI-200 has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 Edition 3.0: 2005+A1:2012 and IEC60601-2-57 Edition 1.0: 2011

- Electromagnetic compatibility test according to IEC 60601-1-2 Edition 4.0: 2014 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"
- The waveform test report has also been conducted to verify the vibration massage pulse's parameters of the device.

11. Usability study and self-selection study summary

A lay-user study and self-selection study was conducted and oversight to determine if lay users could read the product labeling and then self assess if the device would be appropriate for them to use. Study data was collected and demonstrated that the intended users of the device could successfully follow the instructions and use the device as intended. The performance data supplied in this 510(k) demonstrated that 100% of lay users were able to properly self-select themselves using the box labeling and all lay users were able to properly use the device by reading instructions in the user manual without any assistance.
In summary, the conclusion was that an average lay user can read and comprehend correctly the user manual and package labeling.

12. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Photon Vibrating massage Facial Aesthetic Device, Model: UI-200 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.

1) LED functional modes

Elements of Comparison	**Subject Device**	**Predicate Device**		**Remark**
Device Name and Model	Photon Vibrating massage Facial Aesthetic Device, Model: UI-200	Tanda Mini Skincare System	Pulsaderm Acne Device	--
510(k) Number	Applying	K124042	K161941	--
Product Code	OLP, ISA	OLP	OLP	--
Manufacturer	Li-Tek Electronics	Syneron Beauty Inc.	NutraLuxe MD, LLC	--

Elements of Comparison	Subject Device	Predicate Device		Remark
	Technologies			
Intended Use	The Photon Vibrating massage Facial Aesthetic Device (Model: UI-200) is intended for over-the-counter use. LED functional mode - To emit energy in the blue and red region of the spectrum, specifically to treat mild to moderate acne on the face. - To emit energy in the blue region of the spectrum to treat mild to moderate inflammatory acne. Vibrating massage functional mode As an electrically powered device intended for medical purposes to relieve minor aches and pains.	The Tanda Mini Skincare System is generally indicated to treat dermatological conditions. Specifically, blue light modules are indicated to treat mild to moderate inflammatory acne.	Pulsaderm Acne Device is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.	SE Note 1
Basic Unit Characteristics				
Power Source(s)	3.7V 1000mAh Li battery	Battery operated	Battery operated	SE
Method of Line Current Isolation	Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	SE
Weight	180g	--	--	SE Note 2
Dimensions	3.7" L x 7.6" W x 2.8" D	--	--	SE Note 2
Housing Materials and Construction	Housing made from ABS plastic and output contacts made from stainless steel.	--	--	SE Note 2

Elements of Comparison	Subject Device	Predicate Device		Remark
Output Specifications				
Energy Type	LED	LED	LED	SE
LED light Wavelengths	Red: 630 ± 10 nm, Blue: 415 ± 10 nm	Blue:414nm ± 6 nm	Red: 630 ± 5 nm, Blue: 415 ± 5 nm	SE Note 3
LED light Power Density	Blue: 22 mW/cm^2 Red: 7.5 mW/cm^2	Blue:22.4 mW/cm^2	Blue: 20 mW/cm^2 Red: 5 mW/cm^2	SE Note 4
Additional Features				
Environment for Operating	Temperature: 5 ~ 40°C Humidity: ≤ 80%	--	--	SE Note 5
Environment for Storage	Temperature: 0 ~ 45°C Humidity: ≤ 93% RH	--	--	SE Note 5
Biocompatibility	Compliance with ISO10993-5 and ISO10993-10 requirements.	Compliance with ISO10993-5 and ISO10993-10 requirements.	Compliance with ISO10993-5 and ISO10993-10 requirements.	SE
Electrical Safety	Comply with IEC 60601-1 and IEC60601-2-57	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	SE

Comparison in Detail(s):

Note 1 (Intended Use):

For LED irradiation modes, we selected K124042 as predicate device to do substantial equivalence discussion for blue light mode of the subject device, while choose K161941 as the second predicate device to do substantial equivalence discussion for the blue and red light mode.

Although there is minor difference for the expressions of intended use between subject device and predicate devices, they all indicated the same indication for use for each working mode, respectively.

Note 2 (Weight，Dimensions, Materials):

These data would be different for different devices because the internal circuit design and components choosing are different. But weight and dimensions won't affect the safety and

effectiveness of the device since it still belongs to portable device and complied with IEC60601-1. So it would not affect safety and effectiveness of subject device.

Note 3 (LED light Wavelengths):

The LED light wavelengths of the subject device are the same as the predicate device. The wavelengths of blue light mode, comparing between the subject device and K124042, are 415 nm and 414 nm, which are substantially equivalence. The wavelengths of red light, comparing to K161941, are 630 nm, which are substantially equivalence. Therefore, both of blue light wavelength and red light wavelength are the same to the subject device and predict device.

Note 4 (LED light Power Density):

For the LED irradiation mode with red light and blue right, the power density of red light in the subject device is 7.5 mW, but this minor difference of power density would not change lots of LED energy irradiation on the face; and the device pass the testing of IEC60601-2-57, it's safety would not be affected. Therefore, the minor difference of LED power density would not affect the safety and effectiveness of subject device.

Note 5 (Environment for Operating and storage):

These data is to specify the condition of working, transportation and storage. The temperature, RH can be claimed with different condition, and the device pass the testing of IEC60601-1-11. So it can be deemed as the substantially equivalence.

2) Vibrating massage functional mode

Elements of Comparison	**Subject Device**	**Remark**	**Remark**
Device Name and Model	Photon Vibrating massage Facial Aesthetic Device, Model: UI-200	Ultra Renew Plus	--
510(k) Number	Applying	K132833	--
Product Code	OLP, ISA	OLP, OHS, ISA	--
Manufacturer	Li-Tek Electronics Technologies	Accord Media	--
Intended Use	The Photon Vibrating massage Facial Aesthetic Device (Model: UI-200) is intended for over-the-counter use. LED functional mode - To emit energy in the blue and red region	The Accord Media Ultra Renew Plus is intended to be used: LED functional mode - To emit energy in the red and blue region of the spectrum, specifically to treat mild to	SE

Elements of Comparison	Subject Device	Remark	Remark
	of the spectrum, specifically to treat mild to moderate acne on the face. - To emit energy in the blue region of the spectrum to treat mild to moderate inflammatory acne. Vibrating massage functional mode As an electrically powered device intended for medical purposes to relieve minor aches and pains.	moderate acne on the face. - To emit energy in the red region of the spectrum for the treatment of periorbital wrinkles. Ultrasonic functional mode As an electrically powered device intended for medical purposes to relieve minor aches and pains.	
Basic Unit Characteristics			
Power Source(s)	3.7V 1000mAh Li battery	Battery operated	SE
Method of Line Current Isolation	Type BF Applied Part	Type BF Applied Part	SE
Weight	180g	--	SE Note 1
Dimensions	3.7" L x 7.6" W x 2.8" D	--	SE Note 1
Housing Materials and Construction	Housing made from ABS plastic and output contacts made from stainless steel.	--	SE Note 1
Output Specifications			
Vibrating massage Frequency	3MHz ± 5%	3MHz ± 5%	SE Note 2
Additional Features			
Environment for Operating	Temperature: 5 ~ 40°C Humidity: ≤ 80%	--	SE Note 3
Environment for Storage	Temperature: 0 ~ 45°C Humidity: ≤ 93% RH	--	SE Note 3

Elements of Comparison	Subject Device	Remark	Remark
Biocompatibility	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 and IEC60601-2-57	Comply with IEC 60601-1	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1 (Weight，Dimensions, Materials):

These data would be different for different devices because the internal circuit design and components choosing are different. But weight and dimensions won't affect the safety and effectiveness of the device since it still belongs to portable device and complied with IEC60601-1. So it would not affect safety and effectiveness of subject device.

Note 2 (Vibrating massage Frequency):

Both of the ultrasound frequency and the technology principle are the same to the subject device and the predicate device. For the technology principle, the design of both devices is same, and they meant to be pulsed so that therapeutic vibration of the device head at lower frequencies provides massage. Therefore, the subject device and predicate devices are substantially equivalence in Vibrating massage Mode.

Note 3 (Environment for Operating and storage):

These data is to specify the condition of working, transportation and storage. The temperature, RH can be claimed with different condition, and the device pass the testing of IEC60601-1-11. So it can be deemed as the substantially equivalence.

Finial Conclusion:

The subject device " Photon Vibrating massage Facial Aesthetic Device, Model: UI-200" is substantial Equivalence to all predicate devices.