May 25, 2022

Li-Tek Electronics Technology C0., Ltd
℅ Jet Li
Regulation manager
Guangdong Jianda Medical Technology Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, Guangdong
China

Re: K213039
Trade/Device Name: Micro-current facial cold and hot service (model: TPML-100)
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, NFO
Dated: March 29, 2022
Received: April 15, 2022

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213039

Device Name
Micro-current vibration facial cold and hot service (model: TPML-100)

Indications for Use *(Describe)*
Micro-current vibration facial cold and hot service is an over the counter device that is indicated for the treatment of mild to moderate inflammatory acne and facial stimulation for over the counter aesthetic 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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Date of the summary prepared: May 24, 2022

510(k) Summary

K213039

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. This is a ***Traditional 510(K)*** submission, and there were no prior submissions for the subject device.

1. Submitter's Information

Sponsor

- Company Name: Li-Tek Electronics Technology Co., Ltd.
- Address: No. 8~13, the industrial park of Jinshagang, Shixia village, Dalang town, Dongguan city, Guangdong, China
- Phone: + 86-769-83117755
- Email: quality5@li-tek.com
- Contact Person (including title): Barry Yuan (Quality Director)

Application Correspondent:

- Guangdong Jianda Medical Technology Co., Ltd.
- Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China
- Contact Person: Mr. Jett Lee
- Title: Regulation Manager
- Tel: +86-13512755282
- Email: jianda-lee@foxmail.com

2. Subject Device Information

- 510(k) number: K213039
- Type of 510(k) submission: Traditional
- Classification: Over-The-Counter Powered Light Based Laser For Acne;

Transcutaneous electrical nerve stimulator for pain relief

- Trade Name: Micro-current vibration facial cold and hot service
  - Model: TPML-100
  - Review Panel: General& Plastic Surgery / Neurology
  - Product Code: OLP / NFO
  - Regulation Number: 21 CFR 878.4810 / 882.5890
  - Regulation Class: 2

3. Predicate Device Information

Primary Predicate Device I

- 510(k) number: K180900
- Sponsor: UVBIOTEK, LLC
- Classification: Over-The-Counter Powered Light Based Laser For Acne
- Trade Name: LED Light Therapy Device, Model: KN-7000C
- Review Panel: General & Plastic Surgery
- Product Code: OLP
- Regulation Number: 21 CFR 878.4810
- Regulation Class: 2

Secondary Predicate Device II

- 510(k) number: K201906
- Sponsor: LG Electronics, Inc.
- Classification: Transcutaneous electrical nerve stimulator for pain relief
- Trade Name: Trinity ELE Plus Facial Toning Device
- Model: Trinity ELE Plus
- Review Panel: Neurology
- Product Code: NFO
- Regulation Number: 21 CFR 882.5890
- Regulation Class: 2

Predicate Device III

- 510(k) number: K162652
- Sponsor: Li-tek Electronic Technology Corporation.
- Classification: Transcutaneous electrical nerve stimulator for pain relief
- Trade Name: Smart Photon Micro-current Device
- Model: EP-300
- Review Panel: Neurology
- Product Code: NFO
- Regulation Number: 21 CFR 882.5890
- Regulation Class: 2

Reference Device

- 510(k) number: K191951
- Sponsor: Avazzia, Inc.
- Classification: Transcutaneous electrical nerve stimulator for pain relief
- Trade Name: Avazzia OTC TENS for aesthetics
- Model: BEST-AV1™: EZZI-LIFT™ Device
- Review Panel: Neurology
- Product Code: NFO
- Regulation Number: 21 CFR 882.5890
- Regulation Class: 2

4. Device Description

The Micro-current vibration facial cold and hot service device (Model: TPML-100) is a hand-held, non-sterile, reusable device designed to achieve the aesthetic effect. It consists of main unit, and USB cable. The device is supplied by internal rechargeable lithium battery, which can be recharged by external charger through the USB cable. The device is un-usable when charging.

The device is only home environment use, which has three metal heads (Dual / Single), and two LED light windows (Red / Blue) to provides following functions:

a) EMS (micro current output stimulation) function. The device generates a low-frequency micro-current on the Dual Heads which will applied in the facial skin to do facial stimulation.

b) Red and Blue LED irradiation function. The device outputs the red light at the wavelength of 630 ± 10 nm and the blue light at the wavelength of 415 ± 10 nm to apply the light in narrow spectral bandwidth on facial skin to treat mild to moderate acne.

c) Vibration function. The device generates different patterns of micro-vibration by a built-in micro motor to relax the facial skin. (This function is classified as class I and not need for 510K.)

d) Warming and Cooling function. The device heats Dual Heads up to 44 ± 2 ℃ or cool the Single Head down to 10 ± 2 ℃, to relax the facial skin with a warm or cold sensation. (This function is not for medical purpose.)

5. Intended Use / Indications for Use

Micro-current vibration facial cold and hot service is an over the counter device that is indicated for the treatment of mild to moderate inflammatory acne and facial stimulation for the over the counter aesthetic use.

6. Test Summary

Micro-current vibration facial cold and hot service has been evaluated for its safety and performance by lab bench testing as following:

- IEC 60601-1:2012 , Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility

- IEC 60601-1-11:2015 Medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-10:2012 AMD1:2016 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-2-57:2011 Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Micro-current facial cold and hot service is substantially equivalent to the predicate devices quoted above. Even there is minor difference on output waveform parameters and construction between subject device and predicate device. But the differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Device	Proposed Device	Predicate Device I Primary	Predicate Device II Secondary	Predicate Device III Secondary	Reference Device
510(K)	K213039	K180900	K201906	K162652	K191951
Manufacturer	Li-Tek Electronics Technology Co., Ltd	Uvbiotek, LLC	Carol Cole Company dba NūFACE	Li-Tek Electronics Technology Co., Ltd	Avazzia, Inc
Product Name	Micro-current vibration facial cold and hot service TPML-100	LED Light Therapy Device KN-7000C	Trinity ELE Plus Facial Toning Device Trinity ELE Plus	Smart Photon Micro-current Device EP-300	Avazzia OTC TENS for Aesthetics BEST-AV1 EZZI-LIFT Device
Classification	Class II, OLP / NFO 21 CFR878.4810/882.5890	Class II, OLP 21 CFR878.4810	Class II, NFO 21 CFR 882.5890	Class II, NFO/OHS/OLP 21 CFR 882.5890	Class II, NFO 21 CFR 882.5890
Prescription/ OTC	OTC	OTC	OTC	OTC	OTC
Intended Use	Micro-current facial cold and hot service is an over the counter device that is indicated for the treatment of mild to moderate inflammatory acne and facial stimulation for the over the counter aesthetic use.	LED Light Therapy Device is indicated for the treatment of mild to moderate inflammatory acne.	The Trinity ELE Plus and Trinity ELE Plus Pro are intended for facial stimulation and are indicated for over the counter cosmetic use.	For micro current Stimulation mode: The device is intended for Facial stimulation and is indicated for over-the counter aesthetic use.	The Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device is indicated for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.
Power Supply	Charger (not included) input: DC 5V, 1A	Adapter Input: 100-240V a.c. 50/60Hz, 0.5A max.	Unknown	3.7V, 800mAh rechargeable lithium battery	3V

	Internal battery: 3.7Vd.c. 900mAh	Adapter Output: 5V d.c. 2A Main unit input: 5V d.c. 2A/ Internal battery: 3.6Vd.c. 2200mAh			
Battery	Lithium-ion	Lithium-ion	Lithium-ion	Lithium-ion	2* 1.5 V AA batteries
Software Control	YES	YES	YES	YES	YES
Handheld	YES	YES	YES	YES	YES
Effective irradiance	Blue light: 25 mw/cm^2 ±10% Red light: 45 mw/cm^2±10%	Blue light: 25±5 mw/cm^2 Red light: 45±5 mw/cm^2	/	/	/
LED Amount	6 red LEDs 4 blue LEDs	48 red LEDs 48 blue LEDs	/	/	/
Wavelength	Blue light: 415±10 nm Red light: 630±10 nm	Blue light: 417±10 nm Red light: 633±10 nm	/	/	/
Energy Output	User adjustable for EMS	/	User adjustable, variable output frequency, microcurrent continuously alternates and delivered via dual chrome-plated precise wands	User adjustable for EMS	/
Special Requirements	No	No	Requires Conductive Gel	Requires Conductive Gel	No

Waveform Type	Bi-phase square-wave pulse	/	Pulsed Biphasic, Modulated Square	Bi-phase square-wave pulse	positive square wave followed by a damped sinusoidal waveform of variable duration depending on damping and body loading
Maximum Output Voltage	225 mV @500Ω, ±10% 900 mV @2kΩ, ±10% 3.86 V @10kΩ, ±10%	/	170 mV @500Ω, ±10% 688 mV @2kΩ, ±10% 3.4 V @10kΩ, ±10%	1.49V @ 500Ω 2.48V @ 2kΩ 10.6V @ 10kΩ	-42V @ 500Ω -122V @ 2kΩ -348V @ 10kΩ
Maximum Output Current	450 µA @500Ω, ±10% 450 µA @2kΩ, ±10% 386 µA @10kΩ, ±10%	/	243 µA @500Ω, ±10% 245 µA @2kΩ, ±10% 246 µA @10kΩ, ±10%	2.98mA @ 500Ω 1.24mA @ 2kΩ 1.06mA @ 10kΩ	500 µA 363 µA @500Ω, ±20% 117 µA @2kΩ, ±20% 38 µA @10kΩ, ±20%
Pulse Period (Pulse Width)	4ms	/	Varies w/ Frequency (60 msec @ 8.33Hz)	4ms	1.1
Output Frequency (Hz)	57±3Hz	/	0.3 – 50 Hz (Default 8.3 Hz)	60Hz	15 to 121
Net Charge	0 µC @ 500Ω	/	0 µC @ 500Ω	0 µC @ 500Ω	4 µC @ 500Ω
Maximum current density	0.49mA/cm²@500Ω	/	Trinity ELE Plus 0.947 mA/cm² @ 10K Ω Trinity ELE Plus Pro 1.165 mA/cm² @ 10K Ω	0.524mA/cm² @500Ω	Built-in, Y, Brush: 800 µA/cm² @500Ω Pencil: 19,000 µA/cm² @500Ω
Maximum Power	0.20mW/cm²@ 500Ω	/	Trinity ELE Plus 2.331 mW/cm² @ 10K Ω	0.216mW/cm² @500Ω	Built-in, Y, Brush: 500µW/cm² @500Ω

Density			Trinity ELE Plus Pro 3.525 mW/cm² @ 10K Ω		Pencil: 3,500μW/cm² @500Ω
Treatment recommendation	Hold treatment face in contact with skin. Apply blue light for 3minutes per skin area, followed by red light for 3 minutes per skin area. Can be used daily. Apply EMS micro-current for 15 minutes per day. Can be used for 2-3 times per week.	Hold treatment face in contact with skin. Apply blue light for 3minutes per skin area, followed by red light for 3 minutes per skin area. Can be used daily.	Unknown	15 minutes	max duration of use: 60minutes
Main Materials	PC, ABS, Stainless steel (SUS 304)	Rigid ABS Polycarbonate lens cover	ABS Thermoplastic Chromium	PC, ABS, Stainless steel (SUS 304)	Stainless steel 316
Dimension	188(L)×50(W)×55(H)mm	257mm×165mm×70mm (10.1in×6.5in×2.8in)	6.1" H x 2.4" W x 1.2" D	--	2.6" X 4.7" X 1.35"
Net Weight	233 g	174g (6.1 oz)	Unknown	--	5.4 ounces
Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 14971 IEC 62366
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	/

8. Summary for clinical test

No Clinical Test conducted.

9. Usability Testing

Usability testing was conducted to demonstrate that the device and its labeling can meet the following requirements:

1) the lay user can self-select themselves as being appropriate users of this device by the external box labeling,

2) the lay user can apply the treatment safely and correctly according to the instructions for use, and

3) the lay user can understand all indications, contraindications, warnings and precautions, and be able to identify whether they are within any contraindicated group; and be able to understand the user manual.

10. Conclusion

The subject device Micro-current vibration facial cold and hot service has all features of the predicate devices for intended use. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate devices.