April 16, 2021

Heat In A Click LLC
℅ Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510006
China

Re: K202055
Trade/Device Name: Looper (Model: ZX-579S)
Regulation Number: 21 CFR 878.4810
Regulation Name: over-the-counter powered light based laser for acne
Regulatory Class: Class II
Product Code: OLP, OHS
Dated: March 9, 2021
Received: March 12, 2021

Dear Cassie Lee:

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)*
K202055

Device Name
Looper (Model: ZX-579S)

Indications for Use *(Describe)*
Looper (Model: ZX-579S) is a hand-held device for over-the counter aesthetic purposes. The Photon mode red light is indicated for the use in treating wrinkles on the face, and the blue light is indicated 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.

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510(k) Summary of K202055

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

Company Name: Heat In A Click LLC
Establishment Registration Number: 3008929787
Address: 1975 Tigertail Blvd Dania Florida 33034 USA
Phone: 1(954)518-9777
Fax No.: 1(954)320-7984
Contact Person (including title): Guy Levi (CEO)
E-mail: hagar@palmmassager.com

Factory:

510(k) Owner's Name: Hong Qiang Xing (Shenzhen) Electronics Limited
Establishment Registration Number: Applying
Address: 4F., Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen, Guangdong Province, PRC
Phone: +86-755-26423615
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Contact Person (including title): Mr. Xu Jianhua (General Manager)
E-mail: info@sunmas.com

Application Correspondent:

Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Subject Device Information

Common Name: Electrosurgical device for over-the-counter aesthetic use
Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over The Counter Wrinkle Reduction (OHS)
Trade Name: Looper (Model: ZX-579S)

Review Panel: Neurology; General & Plastic Surgery

Product Code: OHS, OLP

Regulation Number: 878.4810, 878.4420

Regulation Class: II

3. Predicate Device Information

Sponsor	Heat In A Click	Li-Tek Electronics Technologies	AEGIS Regulatory, Inc.
Device Name and Model	2 Face / Face Evolution(Model:2 Face / Face Evolution)	LED Phototherapy Device	Elevare Plus
510(k) Number	K171821	K162098	K172909
Product Code	NFO, OHS, OLP	OLP, OHS	OHS
Regulation Number	882.5890	878.4810	878.4810
Regulation Class	II	II	II

4. Device Description

Looper (Model: ZX-579S) is a hand-held device for over-the-counter aesthetic purposes, it's a multifunctional comprehensive beauty instrument. It's combined with the two kinds of operation functions: SONIC and PHOTON mode.

Sonic mode: The Sonic waves can provide vibrating to facial skin. The device provides 5 vibration intensities for users to choose from.

Photon mode: The red light is intended for use in treating wrinkles on the face, and the blue light is intended for the treatment of the mild to moderate inflammatory acne. It emits energy in the red spectrum for the treatment of facial wrinkles. The therapeutic probe is designed for direct contact with the face for treatment.

The Looper device consists of an applicator and charging base. An applicator is a hand-held unit used for treatment. The treatment surface is located at the applicator tip and comes in direct contact with the skin. The charging base charging for the applicator. And there is no external data connection capability (e.g., through USB, Ethernet, WiFi, Bluetooth, etc.) for the device.

There are two keys: the PHOTON key and the SONIC key. The PHOTON is to select red light or blue light and the Sonic is to select the SONIC mode and adjust the strength of the sonic. Both keys can turn on/off the device.

5. Intended Use / Indications for Use

Looper (Model: ZX-579S) is a hand-held device for over-the counter aesthetic purposes. The Photon mode red light is indicated for the use in treating wrinkles on the face, and the blue light is indicated for the treatment of the mild to moderate inflammatory acne.

6. Test Summary

The Looper (Model: ZX-579S) has been evaluated the safety and performance by lab bench testing as following:

- IEC 60601-1: 2005+A1: 2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-11 (Edition 2.0): 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 60601-1-2: 014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic Compatibility.
- IEC 60601-2-57 (First Edition): 2011 for use in conjunction with IEC 60601-1:2005, 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.
- IEC 62133-2 Edition 1.0 2017-02, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.
- IEC 60601-1-6: 2013 (Edition 3.1), Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1: 2015 (First Edition), Medical devices – Application of usability engineering to medical devices.
- IEC 62304: Edition 1.1 2015-06, Medical device software, Software life- cycle processes.
- Self Selection and Usability

7. Comparison to predicate device and conclusion

Although there has some slight differences between with subject device and predicate device, the subject device Looper (model: ZX-579S) is Substantial Equivalence to all predicate devices. Because compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1 (Primary Device)	Predicate Device 2	Predicate Device 3	Remark

Elements of Comparison	Subject Device	Predicate Device 1 (Primary Device)	Predicate Device 2	Predicate Device 3	Remark
Company	Heat In A Click LLC	Heat In A Click	Li-Tek Electronics Technologies	AEGIS Regulatory, Inc.	--
Trade Name	Looper	2 Face / Face Evolution	LED Phototherapy Device	Elevare Plus	--
Classification Name	Light Based over the Counter Wrinkle Reduction, Over-the-counter powered light based for acne	Transcutaneous Electrical, Aesthetic Purposes, Light Based Over The Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne	Light Based over the Counter Wrinkle Reduction, Over-the-counter powered light based for acne	Light Based Over-The-Counter Wrinkle Reduction Device	SE
510(k) Number	K202055	K171821	K162098	K172909	--
Product Code	OHS, OLP	NFO, OHS, OLP	OLP, OHS	OHS	SE
Intended Use / Indications for Use	Looper (Model: ZX-579S) is a hand-held device for over-the counter aesthetic purposes. The Photon mode red light is indicated for the use in treating wrinkles on the face, and the blue light is indicated for the treatment of the mild to moderate inflammatory acne.	The subject device is a hand-held device for over-the counter aesthetic purposes and it's intended use for: (1) The EMS mode is indicated for facial stimulation; (2) The Photon mode: 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	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 Elevare Plus is an Over-the-Counter (OTC) device intended for the use in treating wrinkles on the face.	SE

Elements of Comparison	Subject Device	Predicate Device 1 (Primary Device)	Predicate Device 2	Predicate Device 3	Remark
		inflammatory acne.			
Anatomical Sites	Entire Face	Entire Face	Entire Face	Entire Face	SE
Design	Hand-held device	Hand-held device	Hand-held device	Hand-held device	SE
Target Population	Individuals with wrinkles on face, Individuals with mild to moderate inflammatory acne	Individuals with periorbital wrinkles, Individuals with mild to moderate inflammatory acne	Individuals with periorbital wrinkles, Individuals with mild to moderate inflammatory acne	Individuals with wrinkles on face	SE
Environment of Use	Home	Home	Home	Home	SE
Method of Line current Isolation	Type BF	Type BF	Type BF	Not publicly available	SE
Main Unit Weight	230g	200g	150g	Not publicly available	SE Note 1
Dimensions of device	234.5mm x 30mm x 46mm	158mm x 56mm x 51.5mm	187mm x 65mm x 51 mm	Not publicly available	SE Note 1
Housing Materials of main unit	ABS Plastic & Stainless Steel	ABS Plastic & Stainless Steel	ABS Plastic	Not publicly available	SE
Power Source	DC 3.7V 1000mA Li battery	DC 3.7V 2200mAh	DC 3.7V 1050mA Li battery	2 Li-Ion rechargeable batteries	SE
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes	SE
Automatic Shut Off	Yes	Yes	Yes	Yes	SE
User Override Control?	Yes	Yes	Yes	Yes	SE
Indicators	Indicates for low battery, PHOTON mode information, SONIC mode information, intensity level, Charging Indicator	EMS Mode intensity Indicator lights, Photon Mode working indicator lights, Photon Mode Indicator lights, Charging Indicator	Not publicly available	Not publicly available	SE Note 1
Time Range	3 minutes per	EMS Mode (5	3 minutes per	3 minutes	SE

Elements of Comparison	Subject Device	Predicate Device 1 (Primary Device)	Predicate Device 2	Predicate Device 3	Remark
(minutes)	target area; 2 treatments per week for 6 weeks	minutes) Photon Mode (5~7 minutes)	target area; 2 treatments per week for 6 weeks	daily, 5 days per week for 8 weeks	
Wavelengths	Red: 630±10nm Blue: 415±10nm	Red Light (630nm±3nm Wavelength) Blue Light (415nm±3nm Wavelength)	Red: 630±3nm Blue: 415±3nm	RED: 610, 630, 660, 850nm (±5mm)	SE
The distance between the LEDs to treatment surface	Close to the facial skin	2-3 cm	2-3 cm	Close to the facial skin	SE
Irradiation area	12cm^2±10%	26cm^2±5%	30cm^2±5%	Over 17cm^2	SE Note 2
Irradiances	Red light: 55mW/cm^2±10 % Blue light: 48mW/cm^2±10 %	Red light: 73.26mW/cm^2 ±10% Blue light: 64.10mW/cm^2 ±10%	Red light: 80mW/cm^2±10 % Blue light: 65mW/cm^2±10 %	65mW/cm^2 (±5mW)	SE Note 2
Irradiance source	LED	LED	LED	LED	SE
Visible light LEDs	Yes	Yes	Yes	Yes	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	SE
Safety	IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-57	IEC 60601-1, IEC 60601-2-10 and IEC 60601-2-57	IEC 60601-1 and IEC 60601-2-57	IEC 60601-1, IEC 60601-1-11	SE
Working Environment	Temperature: 5~35℃ Humidity: 10~80%RH Atmospheric pressure: 700hPa~1060 hPa	Not publicly available	Temperature: 5~40℃ Humidity: 10~80%RH Atmospheric pressure: 700hPa~1060 hPa	Not publicly available	SE
Transportation and Storage Environment	Temperature: -10~40℃ Humidity: 5~95%RH Atmospheric pressure: 600hPa~1060 hPa	Not publicly available	Temperature: -10~40℃ Humidity: 5~95%RH Atmospheric pressure: 600hPa~1060 hPa	Not publicly available	SE

Comparison in Detail(s):

Note 1:

Although the "Main Unit Weight", "Dimensions of device", "Power source" and "Indicator" of subject device is different from the predicate devices, they are all compliance with IEC 60601-1 requirement for the product and not affect the safety or effectiveness. So the differences of function specification will not raise any safety or effectiveness issue.

Note 2:

Although the "Irradiation area" and "Irradiance" is a little different from the predicate devices, they are all compliance with IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-57 requirements. So the differences will not raise any safety or effectiveness issue.

Note 3:

The Nature of body contact is skin contact. And the contact duration is less than 24 hours. The materials and manufacturing used for the subject device are identical to those of the device K171821, and the materials have been demonstrated to conform with the following biocompatibility standards:

- 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 delayed-type hypersensitivity

Final Conclusion:

Although there has some slight differences between with subject device and predicate device, the subject device Looper (Model: ZX-579S) is Substantial Equivalence to the predicate devices K171821, K162098 and K172909. Because compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. And the subject meets the same standards as the predicate device, so the differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

8. Date of the summary prepared: 2021-04-16