August 15, 2025

Heat In A Click LLC.
% Cassie Lee
Official Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, Guangdong 510530
China

Re: K251871
Trade/Device Name: FEATHER 01 02 03 04 (Model:01)
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: OHS
Dated: June 16, 2025
Received: June 18, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MARK MACIOS -S
Digitally signed by MARK MACIOS -S
Date: 2025.08.15 13:28:48 -04'00'

for Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251871

Device Name
FEATHER 01 02 03 04 (Model:01)

Indications for Use *(Describe)*
The FEATHER 01 02 03 04 (Model: 01) is an Over the-Counter (OTC) device intended for the use in treating wrinkles on the face.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for K251871

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: August 6, 2025

2. Submitter's Information

Company Name: Heat In A Click LLC
Establishment Registration Number: 3008929787
Address: Numiere 1975 Tigertail blvd Dania FL 33004.
Contact Person (including title): Guy Levi (CEO)
Phone: 843-267-9860
Fax: /
Post code: 33004
Email: Guy@palmnrg.com

Application Correspondent:
Contact Person: Cassie Lee
Company Name: 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

Subject Device Information
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Common Name: Light based over the counter wrinkle reduction
Trade Name: FEATHER 01 02 03 04
Model Name: 01
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulatory Class: II

3. Predicate Device Information

Predicate Device 1
Sponsor: Light Tree Ventures Europe B.V.
Trade Name: LED Eye Perfector, model: EY-36A, EY-36B
Trademark: CurrentBody Skin™
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Common Name: Light based over the counter wrinkle reduction
510(k) Number: K221444
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 2
Sponsor: Light Tree Ventures Europe B.V.
Trade Name: Q-Rejuvalight Pro Facewear
Model Name: P19-0023
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Common Name: Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)
510(k) Number: K230042
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description

FEATHER 01 02 03 04 (Models: 01) is an over-the-counter light emitting diode (LED) device that emits energy for use in dermatology for the treatment of wrinkles. The device works by simultaneously emitting 630nm±10nm, 660nm±10nm, 850nm±10nm wavelengths for the treatment of wrinkles. There is only one power/control key on the device, press and hold it for 1.5s to turn on or off the device. Short press the button to adjust the intensity, the white indicator light means the device is running, the flash quickly indicator light means the device is low on power, the slow flashes indicator light means the device is charging.

5. Intended Use / Indications for Use

The FEATHER 01 02 03 04 (Model: 01) is an Over the-Counter (OTC) device intended for the use in treating wrinkles on the face.

6. Comparison to predicate device

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	Predicate Device 2	Remark
Company	Heat In A Click LLC.	Shenzhen Kaiyan Medical Equipment Co., Ltd	Light Tree Ventures Europe B.V.	--
Trade Name	FEATHER 01 02 03 04	LED Eye Perfector, model: EY-36A, EY-36B	Q-Rejuvalight Pro Facewear	--
510(k) Number	K251871	K221444	K230042	--
Product Code	OHS	OHS	OHS, OLP	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
FDA Device Classification	Class II	Class II	Class II	Same
Intended use/ Indication for Use	The FEATHER 01 02 03 04 (Model: 01) is an Over the-Counter (OTC) device intended for the use in treating wrinkles on the face.	The LED Eye Perfector (Model: EY-36A, EY-36B) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.	The Q-Rejuvalight Pro Facewear (Model: P19-0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
			mild to moderate inflammatory acne.	
Environment of Use	OTC	OTC	OTC	Same
Intended Location of Use	Face	Face (Periorbital region)	Face	Same
Power Source	Lithium battery: 3.7V, 500mAh, 1.85Wh Adapter Input: 100-110v., 50/60Hz Adapter Output: 5V, 1A	Mainunit:3.7V,420mAh lithiumbattery,1.55Wh AdapterInput:100~240Va.c.,50/60Hz Adapter Output: 5Vd.c, 1A	Li-ion Polymer Battery: 3.7V, 600mAh, 2.22Wh	Similar Note 2
Indicators	Yes	Yes	Yes	Same
Wavelengths	630nm±10nm; 660nm±10nm; 850nm±10nm	EY-36A: 605nm, 633nm, 660nm, 830nm EY-36B: 605nm, 625nm, 660nm, 880nm	For Wrinkles: 605nm; 630nm; 660nm; 880nm; For acne: 630nm; 415nm;	Similar Note 3
Irradiance source	LEDs	LEDs	LEDs	Same
Total Intensity (mw/cm^2)	Max. 70 mw /cm^2	65 mw /cm^2	For Wrinkles: 70 mw /cm^2 For acne: 45 mw /cm^2	Same
Treatment time	3 minutes per treatment	3 minutes per treatment	3 minutes per treatment	Same
Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83 IEC 62471 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471 IEC 62133-2	Same

Note 1:

Although the “Intended use/Indication for Use” of the subject device is slightly different from the predicate device K221444 in description and the K230042 including acne treatment, all of them are designed to use same/similar treatment wavelengths for wrinkles treatment on the face with the same or similar irradiance source (LEDs) and intensity. So, the difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note 2:
Although the subject device's description in “Power supply” is slightly different from that of the predicate devices, all of them are powered by Lithium-Ion batteries, which comply with IEC 62133-2’s requirements. Besides, both the subject device and the predicate devices conducted safety tests according to the IEC 60601 series standards, and the test results are in compliance with the safety standards’ requirements. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 3:
Although the subject device's “Wavelengths” is slightly different from that of the predicate devices, the wavelengths used by the subject device can be fully covered by the predicate devices. Besides, the predicate devices (K221444 and K230042) and legally marketed devices (such as K232977, K222377) also demonstrate that red light in 605nm~690nm and infrared light in 820nm~930nm can be safely and effectively used in wrinkles treatment. Furthermore, all of them conducted safety and performance tests according to the IEC 60601 series standards, and the test results are in compliance with the IEC 60601 series standards requirements. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 Medical Electrical Equipment - Part 1: 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 60601-2-57 Edition 2.0 2023-07 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 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-2-83 Edition 1.1 2022-12 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment.
- IEC 62133-2 Edition 5.0 2021-09 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 62471 Edition 1.0 2006-07 Photobiological safety of lamps and lamp systems

2) Software verification and validation

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’S Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a Basic level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

3) Usability validation
Usability testing was conducted on the FEATHER 01 02 03 04 (Models:01), which complies with IEC 62366-1 and IEC 60601-1-6.

7.2 Summary of Clinical Performance
Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

8. Final Conclusion:
The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device K221444 and K230042.