



December 23, 2025

Aura Medical LLC
% Gina Walljasper
Principal Consultant
GPW Enterprises LLC
47 Gatehouse Rd
Bedminster, New Jersey 07921

Re: K252187

Trade/Device Name: Aura Glide (FC40)

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief

Regulatory Class: Class II

Product Code: NFO, OHS, OLP

Dated: November 24, 2025

Received: November 24, 2025

Dear Gina Walljasper:

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252187

?

Please provide the device trade name(s).

?

Aura Glide (FC40)

Please provide your Indications for Use below.

?

The Aura Glide is an over-the-counter handheld device for aesthetic purposes.

(1) The microcurrent mode is indicated for facial stimulation.

(2) The LED mode is intended for the treatment of periorbital wrinkles (red light) and for the treatment of mild to moderate inflammatory acne (blue light).

Please select the types of uses (select one or both, as applicable).

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) Summary (as required by 807.92)

1. SUBMITTER/OWNER:

ALC Enterprises Inc (DBA Aura Medical LLC)
134 Stockton St, 1C
Brooklyn, NY 11206

Contact: Connie Lefkowitz, Managing Partner of Aura Medical LLC
2 Skillman St., Suite 512
Brooklyn, NY 11205
FEI Number: 3011721071
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Application Correspondent:

Gina Walljasper, Principal Consultant
GPW Enterprises LLC
47 Gatehouse Rd
Bedminster, NJ 07921
Tel: (908) 507-6503
Email: gina@walljasperpc.com

Date prepared: December 22, 2025

2. DEVICE NAME:

Trade Name	Aura Glide
Common Name	Stimulator, Transcutaneous Electrical, Aesthetic Purposes; Light Based Over-the-Counter Wrinkle Reduction; Over-the-Counter Powered light based laser for acne.
Classification Name	Stimulator, Transcutaneous Electrical, Aesthetic Purposes; Light Based Over-the-Counter Wrinkle Reduction; Over-the-Counter Powered light based laser for acne.
Device Classification	Class II
Review Panel	Neurology; General & Plastic Surgery
510(k) Number	K252187
Product Code(s)	NFO, OHS, OLP
Regulation Number	21CFR882.5890, 21CFR878.4810

510(k) Summary (as required by 807.92)

3. PREDICATE DEVICE(S): Substantial equivalence is based on following legally marketed device.

Sponsor	Heat In Click
Device Name and Model	2 Face/Face Evolution
510(k) Number	K171821
Regulation Name	Transcutaneous Electrical Nerve Stimulator for Pain Relief
Product Code(s)	NFO, OHS, OLP
Regulation Number	21CFR 882.5890, 21CFR 878.4810
Review Panel	Neurology, General & Plastic Surgery
Regulation Class	Class II

4. DESCRIPTION OF THE DEVICE:

Aura Glide is a lemon shaped handheld device that consists of:

- A main control body that is programmed with preset treatment modes depending on the application at the time of use.
- Two (2) essential attachments that are detachable. Each attachment is specifically designed to sit securely on the main body to ensure proper functionality and stability during use.
 - LED (Light Emitting Diode) Attachment – intended for the treatment of periorbital wrinkles (red light) and for the treatment of mild to moderate acne (blue light).
 - Microcurrent Attachment – indicated for facial stimulation. Microcurrent can be delivered with three (3) levels of intensity; L1 (Gentle; Default), L2 (Standard), and L3 (Strong) depending on user preference.
- Conductive gel (Glide On Primer gel) must be applied prior to starting microcurrent treatment. It enhances conductivity ensuring safe and effective microcurrent treatment.
- The Aura Glide is equipped with a USB-C charging port located on the bottom of the device and an internal rechargeable battery. A USB-C charging cable is provided with every device.

The Aura Glide is an over-the-counter cosmetic device for home use.

5. INDICATIONS FOR USE:

The Aura Glide is an over-the-counter handheld device for aesthetic purposes.

- (1) The microcurrent mode is indicated for facial stimulation.
- (2) The LED mode is intended for the treatment of periorbital wrinkles (red light) and for the treatment of mild to moderate inflammatory acne (blue light).

510(k) Summary (as required by 807.92)

6. TESTING SUMMARY:

Aura Glide has been evaluated for safety and performance has been conducted by laboratory testing for the following:

- IEC 60601-1:2005 + A1:2012 +A2: 2020
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 + A1:2020
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
- IEC 60601-1-11:2015 + A1:2020
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 +A1:2016
Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-2-57:2023
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 TR 60601-4-2:2016
Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical system
- IEC 62366-1:2020
Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62133-2:2017
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 First edition 2006-07
Photobiological safety of lamps and lamp systems
- ISO 10993-5:2009
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021
Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021
Biological evaluation of medical devices - Part 23: Tests for irritation

510(k) Summary (as required by 807.92)

Animal Testing – Animal testing is not necessary to support Substantial Equivalence and therefore no animal testing was conducted.

Clinical Testing – Clinical testing is not needed for this premarket notification to support substantial equivalence.

7. COMPARISON WITH PREDICATE DEVICE:

Comparison in Detail(s):

Element of Comparison	Subject Device (Aura Glide - K252187)	Predicate Device (2 Face/Face Evolution - K171821)	Remark
Manufacturer	Aura Medical	Heat in a Click	--
510K number	K252187	K171821	--
Product Name	Aura Glide	2 Face/Face Evolution	--
Classification Name	Stimulator, Transcutaneous Electrical, Aesthetic Purposes; Light Based Over-the-Counter Wrinkle Reduction, Over-the-Counter Powered light-based laser for acne	Stimulator, Transcutaneous Electrical, Aesthetic Purposes; Light Based Over-the-Counter Wrinkle Reduction, Over-the-Counter Powered light-based laser for acne	SE
Regulation Class	II	II	SE
Regulation Number	21CFR882.5890, 21CFR 878.4810	21CFR882.5890, 21CFR 878.4810	SE
Review Panel	Neurology; General & Plastic Surgery	Neurology; General & Plastic Surgery	SE
Product Code	NFO, OHS, OLP	NFO, OHS, OLP	SE
OTC & Rx	OTC	OTC	SE
Indications for Use			
Indications for Use	The Aura Glide is an over-the-counter handheld device for aesthetic purposes. (1) The microcurrent mode is indicated for facial stimulation. (2) The LED mode is intended for the treatment of periorbital wrinkles (red light) and for the treatment of mild to moderate inflammatory acne (blue light).	2 Face/Face Evolution is a handheld device for over-the-counter aesthetic purposes. (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 inflammatory acne	SE
Treatment Area	Face	Face	SE

510(k) Summary (as required by 807.92)

Element of Comparison	Subject Device (Aura Glide - K252187)	Predicate Device (2 Face/Face Evolution - K171821)	Remark
Device Design			
Design	Hand-held	Hand-held	SE
Environment of Use	Home	Home	SE
Method of Line Current Isolation	Type BF	Type BF	SE
Main Unit Weight	198 g	200 g	Similar See Note a.
Dimensions of Device (mm)[W x L x D]	60mm x 58mm x 98mm	158mm x 56mm x 51.5mm	Similar See Note a.
Housing Materials of the Main Unit	ABS Plastic and Chrome plated metal	ABS Plastic and Stainless Steel	Similar See Note b.
Power Source	Internal rechargeable Lithium battery DC 3.7V 600mAh	Internal rechargeable Lithium battery DC 3.7V 2200mAh	Similar See Note c.
Software/Firmware Microprocessor Control?	Yes	Yes	SE
Automatic Shut Off	Yes	Yes	SE
User Override Control	Yes	Yes	SE
Indicator	Microcurrent intensity indicator lights. LED mode working indicator lights, Charging Indicator	EMS Mode intensity indicator lights. Photon mode working indicator lights, Charging Indicator	SE
Treatment Time	Microcurrent: 8 minutes (preset) LED: 10 minutes (preset)	EMS Mode: 5 minutes Photon Mode: 5 – 7 minutes	Similar See Note d.
Wavelengths	Red Light: 633 nm ± 10nm Blue Light: 415 nm ± 10nm	Red Light: 630 nm ± 3nm Blue Light: 415 nm ± 3nm	Similar See Note e.
LED Power	0.1W	0.1W	SE
Energy emitted during treatment	1050J	1050J	SE
Distance between LEDs to treatment surface	2-3cm	2-3cm	SE
Irradiation Area	22.5cm ² ±5%	26cm ² ±5%	Similar See Note e.
Waveform and Shape	Pulsed Biphasic, Modulated Square	Pulsed Biphasic, Modulated Square	SE

510(k) Summary (as required by 807.92)

Element of Comparison	Subject Device (Aura Glide - K252187)	Predicate Device (2 Face/Face Evolution - K171821)	Remark
Maximum Output Voltage (+/- 10%)	252 mV @ 500Ω 940 mV @ 2000Ω 3.92 V @ 10,000Ω	310 mV @ 500Ω 1.16 V @ 2000Ω 5.56 V @ 10,000Ω	Similar See Note f.
Maximum Output Current (+/- 10%)	504 μA @ 500Ω 470 μA @ 2000Ω 392 μA @ 10,000Ω	620 μA @ 500Ω 580 μA @ 2000Ω 556 μA @ 10,000Ω	Similar See Note f.
Maximum Phase Charge	34.89 μC @ 500Ω	26.31 μC @ 500Ω	Similar See Note f.
Maximum Current Density	0.315 mA.cm ² @500Ω (The minimum electrode size 1.6cm ²)	0.330 mA.cm ² @500Ω (The minimum electrode size 2.91cm ²)	
Maximum Power Density	7.94μW/cm ² @ 500Ω (The minimum electrode size 1.6cm ²)	4.34μW/cm ² @ 500Ω (The minimum electrode size 2.91cm ²)	Similar See Note f.
Pulse Duration	60ms	60ms	SE
Irradiance Source	LED	LED	SE
Visible Light LEDs	Yes	Yes	SE
Compliance with 21 CFR 898	Yes	Yes	SE
Testing Summary			
EMC	IEC 60601-1-2	IEC 60601-1-2	SE
Safety	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-10 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-2-10 IEC 60601-2-57	SE
Biocompatibility	ISO 10993-5 (Cytotoxicity) ISO 10993-10 (Skin Sensitization) ISO 10993-23 (Irritation)	ISO 10993-5 (Cytotoxicity) ISO 10993-10 (Irritation and Skin Sensitization)	SE
Battery	IEC 62133-2	IEC 62133-2	SE
Usability	IEC 60601-1-6 IEC 62366 -1 Light Power Density	IEC 60601-1-6 IEC 62366	SE

510(k) Summary (as required by 807.92)

8. NOTES:

- a. The minor differences in weight and dimensions are due to the difference in design, appearance, and shape of the main body for both the subject and predicate devices. Both devices are designed to be handheld and used in a home environment. The minor differences in weight and dimensions pose no safety or effectiveness concerns or issues as demonstrated by the safety and performance testing conducted.
- b. Stainless steel is used in the manufacture of the Predicate device and the microcurrent spheres are chrome plated on the Subject device, Aura Glide, this minor difference poses no concern for safety or effectiveness. The difference between stainless steel and chrome plating does not affect the safety and/or effectiveness of the Subject device as provided in the ISO 10993-5, ISO 10993-10, and ISO 10993-23 Biocompatibility reports.

The Subject device, Aura Glide, also has a plastic shield covering the LED lights in the LED attachment. This information was not available for the Predicate device. The plastic used on the subject device is among the list of synthetic polymers that pose low biocompatibility risk because of the long history of safe use in other legally marketed devices that contact intact skin.

- c. The Subject device, Aura Glide, has been evaluated and found to comply with the safety standards as required per IEC 60601-1 and IEC 62133-2. Therefore, the minor difference in Power Source poses no effect on safety and/or effectiveness.
- d. The preset treatment time for microcurrent and LED are slightly different between the Subject and Predicate devices. The preset treatment time for the Subject device is based on current user practice. Based on user preference, the user can also manually turn off the device at any time before the treatment ends. This minor difference poses no safety and/or effectiveness concerns.
- e. The differences in Wavelength and Irradiation Area between the Subject and Predicate devices are very minor and well within their tolerance that the differences do not pose any concerns with regards to safety and/or effectiveness.
- f. The Subject device, Aura Glide, has been evaluated extensively and found to comply with the safety standards set forth in IEC 60601-1, IEC 60601-1-11, IEC 60601-2-10, and IES 60601-2-57. The minor differences in maximum output voltage, maximum output current, maximum phase charge and maximum power density poses no adverse effect on safety and/or effectiveness.

510(k) Summary (as required by 807.92)

9. CONCLUSION:

The Aura Glide is substantially equivalent to the predicate device with regards to the indications for use, and overall technological characteristics. Any minor differences that may exist between the subject and predicate devices do not raise questions of safety and effectiveness based on satisfactory test results obtained from safety and performance testing conducted. Thus, the Aura Glide is as safe, and as effective, as the predicate device.