April 26, 2018

Heat In A Click
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, Guangdong 510006 CN

Re: K171821
Trade/Device Name: 2 Face / Face Evolution
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: March 22, 2018
Received: March 26, 2018

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. 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K171821

Device Name
2 Face / Face Evolution

Indications for Use *(Describe)*
2 Face / Face Evolution is a hand-held 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.

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.

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**Chapter 5. 510(k) Summary**

# 510(k) Summary

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

**Date of the summary prepared: April 26, 2018**

**1. Submitter's Information**

Company Name: Heat In A Click

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

**Application Correspondent:**

Contact Person: Ms. Cassie Lee

Guangzhou GLOMED Biological Technology Co., Ltd.

Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China

Tel: +86-20-61099984

Email: regulatory@glomed-info.com

**2. Subject Device Information**

Type of 510(k): Traditional
Common Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes; Light Based Over the Counter Wrinkle Reduction, over-the counter powered light based laser for acne
Review Panel: Neurology; General & Plastic Surgery

Trade Name: 2 Face / Face Evolution (Model: 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

Review Panel: Neurology; General & Plastic Surgery

Product code: NFO, OHS, OLP

Regulation Number: 882.5890, 878.4810

Regulation Class: 2

**3. Predicate Device Information**

| | | |
|---|---|---|
| **Sponsor** | Carol Cole Company | Li-Tek Electronics Technologies |
| **Device Name and Model** | NUFACE® Plus | LED Phototherapy (PL-120) |
| **510(k) Number** | K103472 | K162098 |
| **Product Code** | NFO | OLP, OHS |
| **Regulation Number** | 882.5890 | 878.4810 |
| **Regulation Class** | II | II |

**4. Device Description**

2 Face / Face Evolution (Model: 2 Face / Face Evolution) is consists of a Main Unit, conductive gel, charger and user manual, it's a multifunctional comprehensive beauty instrument. It's combined with the most effective two kinds of techniques of internationally recognized skin care:
The EMS Mode is intended for facial stimulation for aesthetic purposes. It produces microcurrent discharged through the EMS Mode treatment probe. Microcurrent is an aesthetic modality providing electric current in millionths of an ampere. The EMS mode is indicated for aesthetic facial stimulation and requires the use of conductive gel. 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. It emits energy in the red spectrum for the treatment of periorbital wrinkles. The PHOTON Mode treatment probe is designed for contact with the face. The device continually pulses the light output, and provides 4 kinds of output intensity level.

**5. Intended Use / Indications for Use**

2 Face / Face Evolution is a hand-held 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.

**6. Test Summary**

2 Face / Face Evolution has been evaluated the safety and performance by lab bench testing as following:

- AAMI / ANSI / ISO 10993-5:2009/(R) 2014, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity. (Biocompatibility).
- ISO 10993-10 Third Edition 2010-08-01, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization. (Biocompatibility).
- IEC / EN 60601-1-2: 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic Compatibility.
- IEC 60601-2-11 (First Edition):2010, 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 60601-2-57 (First Edition): 2011 for use in conjunction with IEC 60601-1:2005, Medical electrical equipment -- Part 2: 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 60601-1-6: 2010 (Third Edition), Medical electrical equipment – Part 1-6 General requirements for safety – Collateral Standard: Usability
- IEC 60601-2-10: 2012 (Second Edition), medical electrical equipment -- part 2-10: particular requirements for the basic safety and essential performance of nerve and muscle stimulators. (Neurology)
- IEC 62133 Edition 2.0 2012-12, 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
- IEC 62366: 2007 (First Edition) + A1: 2014, Medical devices – Application of usability engineering to medical devices
- IEC 62304: 2006 (First Edition), Medical device software, Software life- cycle processes.

**7. Comparison to predicate device and conclusion**

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** | | **Remark** |
|---|---|---|---|---|
| Manufacturer | Heat In A Click | Carol Cole Company | Li-Tek Electronics Technologies | -- |
| Device Name and Model | 2 Face / Face Evolution | NuFace® Plus | LED Phototherapy (PL-120) | -- |
| 510(k) Number | K171821 | K103472 | K162098 | -- |
| Product Code | NFO, OHS, OLP | NFO | OLP, OHS | SE |
| Indications for Use | 2 Face / Face Evolution is a hand-held device for over-the counter aesthetic purposes.<br>(1) The EMS mode is indicated for facial stimulation;<br>(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. | The NūFace® Plus Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use. | 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<br>Note 1 |
| Anatomical Sites | Entire Face | Entire Face | Entire Face | SE |
| Design | Hand-held device | Hand-held device | Hand-held device | SE |
| Target Population | Individuals with periorbital wrinkles, Individuals with mild to moderate inflammatory acne | Individuals seeking facial simulation for aesthetic purposes | Individuals with periorbital wrinkles; Individuals with mild to moderate inflammatory acne | SE |
| Environment of Use | Home | Home | Home | SE |
| Method of Line current Isolation | Type BF | Type BF | Type BF | SE |
| Main Unit Weight | 200g | 9oz without charging base | 150g | SE<br>Note 2 |
| Dimensions of device (inch)[W x LxD] | 158mm*56mm*51.5mm | 3"x 5.25"x 1.25" | 187mm*65mm*51mm | SE<br>Note 2 |
| Housing Materials of main unit | ABS Plastic & Stainless Steel | Thermo Plastic | ABS Plastic | SE<br>Note 2 |
| Power Source | DC 3.7V 2200mAh | 4 rechargeable AA | DC 3.7V 1050mAh | SE |

| | | NiMH batteries | Li battery | Note 2 |
|---|---|---|---|---|
| Average DC current through electrodes when device is on but no pulses are being applied | 0A | 0A | -- | SE |
| Number of Output channels | 2 | 1 | -- | SE Note 2 |
| Regulated Current or Regulated Voltage? | Both | Both | -- | SE |
| Software/Firmware/Microprocessor Control? | Yes | Yes | Yes | SE |
| Automatic Overload Trip? | No | No | Yes | SE |
| Automatic Shut Off | Yes | Yes | Yes | SE |
| User Override Control? | Yes | Yes | Yes | SE |
| Indicator | EMS Mode intensity Indicator lights, Photon Mode working indicator lights, Photon Mode Indicator lights, Charging Indicator | Indicates on/off status, low battery and voltage / current level. | -- | SE Note 2 |
| Time Range (minutes) | EMS Mode (5 minutes) Photon Mode (5~7 minutes) | 21 minutes | 3 minutes per target area; 2 treatment per week for 6 weeks | SE Note 2 |
| Wavelengths | Red Light (630nm±3nm Wavelength), Blue Light (415nm±3nm Wavelength) | -- | Blue light: 415nm±3nm Red light: 630nm±3nm | SE Note 3 |
| LED power | 0.1 W | -- | 0.1 W | SE |
| Energy emitted during the treatment | 1050J | -- | 1080J | SE Note 3 |
| The distance between the LEDs to treatment treatment surface | 2-3 cm | -- | 2-3 cm | SE |
| Irradiation area | 26cm²±5% | -- | 30cm²±5% | SE Note 3 |

| | | | | |
|---|---|---|---|---|
| Irradiances | Red light: 73.26 mW/cm$^2$±10%<br>Blue light: 64.10 mW/cm$^2$±10% | -- | Red light: 80 mW/cm$^2$ ±10%<br>Blue light: 65 mW/cm$^2$±10% | SE<br>Note 4 |
| Waveform and Shape | Pulsed Biphasic, Modulated Square | Pulsed MonoPhasic, Modulated Square | -- | SE<br>Note 3 |
| Maximum Output Voltage (+/- 10%) | 310mV @ 500Ω<br>1.16V @ 2kΩ<br>5.56V @ 10kΩ | 137 mV @ 500Ω<br>769 mV @ 2 kΩ<br>3.82 V @ 10 kΩ | -- | SE<br>Note 3 |
| Maximum Output Current (+/- 10%) | 620μA @ 500Ω<br>580μA @ 2kΩ<br>556μA @ 10kΩ | 274μA @ 500Ω<br>387μA @ 2kΩ<br>283μA @ 10kΩ | -- | SE<br>Note 3 |
| Maximum Phase Charge | 26.31μC @ 500Ω | 23.06μC @ 500Ω | -- | SE<br>Note 3 |
| Maximum Current Density | 0.330mA/cm$^2$ @500Ω<br>(The Minimum Electrode Size: 2.91cm²) | 0.419 mA/cm$^2$@500Ω | -- | SE<br>Note 3 |
| Maximum Power Density | 4.34μW/cm$^2$ @500Ω<br>(The Minimum Electrode Size: 2.91cm²) | 3.22μW/cm$^2$@500 Ω | -- | SE<br>Note 3 |
| Pulse Duration | 60ms | 119ms | -- | SE<br>Note 3 |
| Frequency | 8.333Hz | 8.4Hz | -- | SE<br>Note 3 |
| Irradiance source | LED | -- | LED | SE<br>Note 3 |
| Visible light LEDs | Yes | Yes | Yes | SE |
| Compliance with 21 CFR 898 | Yes | Yes | Yes | SE |
| EMC | IEC 60601-1-2 | EN 60601-1-2 | IEC 60601-2 | SE |
| Safety | IEC 60601-1, IEC 60601-2-10 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 | SE |

**Comparison in Detail(s):**

**Note 1**

We find that the combined the predicate devices NuFace® Plus (K103472), LED Phototherapy (PL-120) (K162098) can be equivalent to the subject device per the predicates' 510(k) summary. So the differences will not raise any safety or effectiveness issue.

**Note 2**

Although the Main Unit Weight, Dimensions of device, Housing Materials of main unit, Power source, Number of Output channels, Indicator and Time Range of subject device is different from the predicate devices, they are all compliance with IEC 60601-1 and IEC 60601-2-10 requirement for the product. So the differences of function specification will not raise any safety or effectiveness issue.

**Note 3**

Although the Wavelengths, Energy emitted during the treatment, Irradiation area, Waveform and Shape, Maximum Output Voltage, Maximum Output Current, Maximum Phase Charge, Maximum Current Density, Maximum Power Density, Pulse Duration, Frequency and Irradiance source is a little different from the predicate devices, they are all compliance with IEC 60601-1 and IEC 60601-2-57 requirements. So the differences will not raise any safety or effectiveness issue.

**Note 4**

Although the Irradiances is a little different from the predicate devices, but they are within the deviation range, so the differences will not raise any safety or effectiveness issue.

**Final Conclusion:**

The subject device “2 Face / Face Evolution” is Substantial Equivalent to the predicate devices.