April 2, 2022

Carol Cole Company dba NuFACE
% Bob Duffy
President
Bob Duffy Associates, Inc.
16405 Summer Sage Rd.
Poway, California 92064

Re: K212947
Trade/Device Name: Trinity Plus Wrinkle Reducer
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: [NOTE: Use date of most recent supplement]
Received: September 15, 2021

Dear Bob Duffy:

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)*
K212947

Device Name
Trinity Plus Wrinkle Reducer

Indications for Use *(Describe)*

The Trinity Plus Wrinkle Reducer is an over-the-counter hand-held device intended for reduction of full-face fine lines and wrinkles, and increase in local circulation within the perioral region.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements established by 21 CFR 807.92.

1. Submitter/Owner

Carol Cole Company dba NūFACE
1325 Sycamore Ave, Suite A
Vista, CA 92081 (USA)

Contact Person: Tera Peterson
Chief Executive Officer
Phone: (760) 509-1187
Email: tpeterson@myNuFACE.com

Date Prepared: March 30, 2022

2. Subject Device

Device Trade / Proprietary Name:	Trinity Plus Wrinkle Reducer
Device Common or Usual Name:	Light based over the counter wrinkle reduction device
Regulation Number:	21 CFR 878.4810
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	OHS
FDA Panel:	79 - General and Plastic Surgery
Class:	II

3. Predicate Devices

Legally marketed predicate devices to which the Carol Cole Company dba NūFACE is claiming substantial equivalence to:

510(k) Number	K120560	K172662
Manufacturer	Carol Cole Company dba NūFACE	LED Technologies, Inc
Trade Name	NūFACE® Trinity Wrinkle Remover	reVive Perioral LED Light Therapy System
Product Code	OHS	OHS, ILY
Regulation Number	21 CFR 878.4810	
Classification Name	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology	
FDA Panel	79 - General and Plastic Surgery	
Class	II	

4. Device Description

The Trinity Plus Wrinkle Reducer (hereinafter referred to as "TWR Plus") comprises the TWR Plus main body, a TWR Plus light attachment head, a charging cradle, and a wall-mount power adaptor. The device and all its associated components are reusable and provided non-sterile.

The TWR Plus is a hand-held phototherapy device that emits Red and Infrared (IR) light energy in the 605, 630, 645, 660 and 855 nanometer wavelengths via a light attachment head. The light attachment head comprises (34) Light Emitting Diodes (LED's) which are the source of the light energy. The Red and IR light energy is used in the treatment of fine lines and wrinkles around eyes, mouth, and forehead and promotes local blood circulation.

The subject device includes three indicator LED's, one internal speaker and one vibration motor. These features provide visual, audible, and haptic feedback to the user during normal operation. The light attachment head includes a proximity sensor to detect when device is pressed onto the skin.

The subject device is turned on and turned off via a dedicated ON/OFF button. Once the subject device is ON, the user follows the provided Instructions for Use to start the treatment. The ON/OFF button also serves as a multi-function User Interface (UI) button by allowing the User to control other functions while the subject device is in Standby, Treating, Charging or Sleep modes. A long press of approximately one second on the ON/OFF button can stop treatment at any time.

Upon power up, the three indicator lights turn on and an ascending audible beep is emitted notifying the user that the device is ON. Once the device is ON, the light therapy LEDs are set to a visible, but significantly dimmed non-treatment state. As the device is placed in direct contact with the skin, the proximity sensor will turn the light therapy LEDs on to start the treatment. While in treatment, if the device is moved away from the skin, the device emits three beeps, and the LEDs revert to the significantly dimmed non-treatment state. The device also emits two beeps to inform the user when a treatment interval is complete and that it is time to treat another section of skin. The device automatically Shuts OFF after 24 minutes of use to indicate the treatment is complete.

The device is powered by one internal rechargeable, non-removable battery which is charged via a provided wireless charging cradle. The charging cradle is powered by a pre-approved wall-mount power supply. The light energy output power is zero watts while the device is in the charging cradle or when turned off. All charging circuitry is contained within the handheld unit itself.

The housings of TWR Plus main body, the light attachment head and the charging cradle are made from injection molded thermoplastic resins. The lens of the light attachment head, which is intended to come in contact with the skin, is made from a biocompatible polymer material. The TWR Plus, including the light attachment head, measures 5.4" H x 2.6" W x 1.7" D and weighs 7.8 oz. The charging cradle measures 2.3" H x 3.0" W x 2.7" D and weighs 7.30 oz.

The TWR Plus uses Bluetooth Low Energy (BLE) wireless technology to pair to and connect with compatible devices capable of running the NūFACE® App. The NūFACE® App allows the user to select and run pre-programmed treatment profiles stored in the device.

Device component list:

1 x TWR Plus Main Body
1 x TWR Plus Light Attachment Head
1 x Wireless Charging Cradle
1 x Pre-approved wall-mount power adaptor

5. Indications for Use

The Trinity Plus Wrinkle Reducer is an over-the-counter hand-held device intended for the reduction of full-face fine lines and wrinkles, and increase in local circulation within the perioral region.

6. Device Comparison Table

Item	Subject Device	Predicate Device (K120560)	Predicate Device (K172662)
Type of Energy Output	IR and Red light	IR and Red light	IR and Red light
Energy Delivery	Electromagnetic energy is radiated via an array of LEDs	Electromagnetic energy is radiated via an array of LEDs	Electromagnetic energy is radiated via an array of LEDs
Wavelength Range	605, 630, 645, 660 and 855 nm	605, 630, 660 and 855 nm	605, 630, 660 and 880 nm
Energy Output Level	Fixed, not user adjustable	Fixed, not user adjustable	Fixed, not user adjustable
Energy Power Source	Internal Rechargeable Battery	Internal Rechargeable Battery	Internal Rechargeable Battery
Power Accessories	Device-specific charging cradle	Device-specific charging cradle	Universal USB charger cord
Charging Method	Wireless charging	Contact charging	Contact charging
Battery Type	Lithium-Ion	Nickel-Metal Hydride	Lithium-Ion
Power Supply Type	Pre-approved wall-mount Power Adaptor	Pre-approved wall-mount Power Adaptor	USB Power Supply
Wireless Technology	*Bluetooth*® Low Energy (BLE)	None	None

The devices use the same type of red and infrared LED technology, and the proposed light-emitting device does not raise new types of questions regarding safety and efficacy for the proposed indications for use. Although there are differences between the proposed and predicate devices, performance testing discussed below supports that the proposed device can be used safely and effectively for the proposed indications for use.

7. Non-Clinical Performance Data

7.1. Summary of Testing Performed

A program of design verification and validation testing and evaluation was conducted that includes the following:

- Biocompatibility Evaluation
- Safety, Performance and Bench Testing including EMC
- Software Verification and Validation Testing

7.2. Conclusions from Biocompatibility Evaluation

A biocompatibility conclusions summary for the all patient-contacting materials is presented below.

Material	**Where Used**	**Nature of body contact**	**Conclusion**
ABS Thermoplastic	Enclosures (housings) for the subject device main body, the light attachment head and the charging cradle and wall-mount power supply	Surface device, intact skin, limited (<24h) duration.	Biocompatible. This material is used in other FDA-cleared devices.
Polymer	Lens of the light attachment head		Biocompatible. Per manufacturer's Certificate of Compliance for ISO 10993 Biocompatibility tests.

7.3. Conclusions from Safety, Performance and Bench Testing

The safety and performance testing results for Optical Safety, Electrical Safety, EMC, Wireless Coexistence and bench testing concluded that the TWR Plus device meets and complies with the safety and performance of the applicable standards and bench testing requirements.

7.4. Conclusions from Software Verification and Validation

The software verification and validation results concluded that the TWR Plus device meets and complies with the applicable software requirements specifications.

7.5. Animal Testing

The substantial equivalence for the subject device will not be supported by animal testing. Therefore, no animal testing was conducted.

7.6. Clinical Testing

Clinical testing was not considered to be needed in this premarket notification in order to support substantial equivalence.

8. Overall Conclusion

The documentation and test results provided in this submission and comparison of intended use, principle of operation, performance data, design and the overall technological characteristics, demonstrate that the NūFACE® Trinity Plus Wrinkle Reducer device is substantially equivalent to the predicate device.