February 24, 2021

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

Re: K201906
Trade/Device Name: Trinity ELE Plus and Trinity ELE Plus Pro
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: January 20, 2021
Received: January 25, 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,

Heather Dean, PhD
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

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)*
K201906

Device Name

Trinity ELE Plus and Trinity ELE Plus Pro

Indications for Use *(Describe)*

The Trinity ELE Plus and Trinity ELE Plus Pro devices are intended for facial stimulation and are indicated for over-the counter cosmetic use.

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. 510(k) 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: February 23, 2021

2. Subject Device Name

Device Trade / Proprietary Name:	Trinity ELE Plus and Trinity ELE Plus Pro
Device Common or Usual Name:	Trinity ELE Plus Facial Toning Device
Regulation Number:	21 CFR 882.5890
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	NFO
FDA Panel:	84 - Neurology
Class:	II

3. Predicate Device

Below is information on the legally marketed predicate device to which the Carol Cole Company dba NūFACE is claiming substantial equivalence to:

510(k) Number:	K131251
Manufacturer:	Carol Cole Company dba NūFACE
Trade Name:	Trinity ELE
Regulation Number:	21 CFR 882.5890
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	NFO
FDA Panel:	84 - Neurology
Class:	II

4. Reference Device

Below is information on the legally marketed predicate device which the Carol Cole Company dba NūFACE is using as a reference device:

510(k) Number:	K103472
Manufacturer:	Carol Cole Company dba NūFACE
Trade Name:	NūFACE® Plus
Regulation Number:	21 CFR 882.5890
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief

Product Code:	NFO
FDA Panel:	84 - Neurology
Class:	II

5. Device Description

The Trinity ELE Plus comprises the Trinity ELE Plus device main body, a Trinity ELE Plus microcurrent attachment head, a charging cradle, and a wall-mount power adaptor. A tube of NūFACE® Gel Primer is provided with the subject device as an accessory. The subject device and all its associated components and accessories are reusable and provided non-sterile.

The Trinity ELE Plus is a hand-held device that produces low levels of microcurrent which is discharged through two dual chrome-plated precise wands for aesthetic purposes. The device provides audible feedback to inform the user to relocate the device to treat a new location on the skin. The device also includes “hum” features to guide the user during the treatment cycle.

The subject device is powered by one internal rechargeable, non-removable battery which is charged via a provided wireless charging cradle. The charging cradle connects to a provided wall-mount power adaptor. Microcurrent output is cut-off while the device is sitting on the charging cradle either charging the battery or when the battery is fully charged.

The enclosures of the subject device main body, the attachment head and the charging cradle are made from injection molded ABS thermoplastic material. The same ABS material is used in other FDA-cleared devices. The dual chrome-plated precise wands on the attachment head use chromium. The same chromium material is used in the predicate device dual chrome-plated precise wands.

The subject device, including the attachment head, measures 6.1" H x 2.4" W x 1.2" D. The charging cradle measures 2.3" H x 3.0" W x 2.7" D.

The device includes an ‘ON/OFF’ multi-function button to turn the device on and off, start and stop treatment, increase or decrease the microcurrent output level and pair with a smart device. The device also includes a “BOOST” button that temporarily increases the microcurrent output level.

The device includes indicator LED’s to provide information to the user on the status of the device and the progress of the treatment.

The subject device is the capable of pairing with compatible smart devices using Bluetooth Low Energy (BLE) wireless communications technology. This technology allows the subject device to communicate with other devices running the NūFACE® App which allows the user to select and run pre-programmed treatment profiles.

The Trinity ELE Plus provides microcurrent output at selected frequencies from 0.3 to 50 Hz.

The Trinity ELE Plus is available in two models, a Standard model and a ‘Pro” model. The Trinity ELE Plus Standard model has a maximum output current without Boost of 170 μA, and the Trinity ELE Plus Pro model has a maximum output current without Boost of 200 μA. All other aspects of the Trinity ELE Plus except those related to maximum output current, are the same between the Standard model and Pro models.

6. Intended Use

The Trinity ELE Plus is intended for facial stimulation and is indicated for over-the-counter cosmetic use.

7. Technological Characteristics

Item	Subject Device	Predicate Device	Same / Different
Type of Energy Output	Microcurrent	Microcurrent	Same
Energy Delivery	Microcurrent is delivered via dual chrome-plated precise wands (optimized for contact with the skin)	Microcurrent is delivered via dual chrome-plated precise wands (optimized for contact with the skin)	Same
Energy Flow	Microcurrent continuously alternates between the positive and negative wands	Microcurrent continuously alternates between the positive and negative wands	Same
Energy Output	User adjustable	User adjustable	Same
Microcurrent Boost	Yes, Temporary, User controllable	No	Different
Energy Power Source	Internal Rechargeable Lithium Ion Battery	Internal Rechargeable NiMH Battery	Different
Power Accessories	Device-specific charging cradle	Device-specific charging cradle	Same
Charging Method	Wireless charging	Contact charging	Different
Charging Circuitry	Internal to Device	Internal to Device	Same
Power Supply Type	Pre-approved wall-mount Power Adaptor	Pre-approved wall-mount Power Adaptor	Same
Special Requirements	Requires Conductive Gel	Requires Conductive Gel	Same
Wireless Technology	Bluetooth Low Energy (BLE)	None	Different
Output Frequency	Variable	Fixed	Different

8. Output Specifications

The Table below reflects the results of the testing performed to demonstrate substantial equivalence to the predicate.

Item	Subject Device Specification	Predicate Device Specification	Same / Different
Waveform Type	Pulsed Biphasic	Pulsed Biphasic	Same
Shape (e.g., rectangular, spike)	Modulated Square	Modulated Square	Same

Item	Subject Device Specification	Predicate Device Specification	Same / Different
Maximum Output Voltage	Trinity ELE Plus 170 mV @ 500 Ω 688 mV @ 2 kΩ 3.4 V @ 10 kΩ Trinity ELE Plus Pro 208 mV @ 500 Ω 840 mV @ 2 kΩ 4.3 V @ 10 kΩ	68 mV @ 500 Ω 283 mV @ 2 kΩ 1.31 V @ 10 kΩ	Different
Maximum Output Current	Trinity ELE Plus 243 µA @ 500 Ω 245 µA @ 2 kΩ 246 µA @ 10 kΩ Trinity ELE Plus Pro 297 µA @ 500 Ω 299 µA @ 2 kΩ 301 µA @ 10 kΩ	135 µA @ 500 Ω 134 µA @ 2 kΩ 133 µA @ 10 kΩ	Different
Output Tolerance	+/- 10% (RMS)	+/- 2%	Different
Pulse Period (Pulse Width)	Varies w/ Frequency (60 msec @ 8.33Hz)	60 msec	Different
Output Frequency (Hz)	0.3 – 50 Hz (Default 8.3 Hz)	8.3 Hz	Different
For Interferential Waveforms Only			
Beat Frequency (Hz)	No Beat Frequency	No Beat Frequency	Same
For Multiphasic Modes Only			
Symmetrical Phases	Not Multiphasic	Not Multiphasic	Same
Phase Duration	Not Determined	Not Determined	Same
Net Charge (µC per pulse)	N/A - Battery Operated	N/A - Battery Operated	Same
Maximum phase charge	Trinity ELE Plus 14.78 µC @ 10K Ω Trinity ELE Plus Pro 18.17 µC @ 10K Ω	8.08 µC @ 500 Ω	Different

Item	Subject Device Specification	Predicate Device Specification	Same / Different
Maximum current density	Trinity ELE Plus 0.947 mA/cm² @ 10K Ω Trinity ELE Plus Pro 1.165 mA/cm² @ 10K Ω	0.519 mA/cm² @ 500 Ω	Different
Maximum power density (µW/cm²)	Trinity ELE Plus 2.331 mW/cm² @ 10K Ω Trinity ELE Plus Pro 3.525 mW/cm² @ 10K Ω	670 µW/cm² @ 500 Ω	Different
Burst mode information			
a. Pulses per burst	20	20	Same
b. Pulses per second	Varies w/ Frequency (8.3 @ 8.33Hz)	8.3	Same
c. Burst duration (sec)	Varies w/ Frequency (2.4 @ 8.33Hz)	2.4	Same
d. Duty Cycle (%)	50	50	Same
ON time	Varies w/ Frequency (60ms @ 8.33Hz @ 50% Duty Cycle)	60ms	Different
OFF time	Varies w/ Frequency (60ms @ 8.33Hz @ 50% Duty Cycle)	60ms	Different

The Microcurrent Boost can temporarily increase the microcurrent output to a level that exceeds that of the predicate device. However, the increased microcurrent level does not exceed that of a legally marketed reference device with the same intended use and classification, and therefore does not affect the safety and effectiveness of the subject device when used as labeled.

The wireless charging, while different from the contact charging used in the predicate device, only affects the method used to charge the subject device when not in use. Therefore, this difference does not affect the safety and effectiveness of the subject device when used as labeled.

The Bluetooth Low Energy (BLE) wireless technology only allows the subject device to communicate with other devices running the NūFACE® App which allows the user to select and run pre-programmed treatment profiles. Since the pre-programmed treatment profiles are already provided in the device software, this difference does not affect the safety and effectiveness of the subject device when used as labeled.

9. Non-Clinical Performance Data

9.1. 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

9.2. Conclusions from Biocompatibility Evaluation

A biocompatibility conclusions summary for the all patient-contacting materials is presented below. These conclusions are described fully in detail in Section 15 of this premarket notification.

Main Body / Attachment Head / Charging Cradle:

Material	Where Used	Nature of body contact	Conclusion
ABS Thermoplastic	Enclosures (housings) for the subject device main body, the attachment head and the charging cradle.	Surface device, intact skin, limited (<24h) duration.	Biocompatible. This material is used in other FDA-cleared devices.
Chromium	Plated over the two precise wands that are part of the attachment head.	Surface device, intact skin, limited (<24h) duration.	Biocompatible. Material and manufacturing process are the same as the predicate.

Wall-mount Power Adaptor:

Material	Where Used	Nature of body contact	Conclusion
ABS Thermoplastic	Power Adaptor main body enclosure.	Surface device, intact skin, limited (<24h) duration.	Biocompatible. The power adaptor is identical to the power adaptor of the predicate device.

Gel Primer:

Material	Where Used	Nature of body contact	Conclusion
NūFACE® Gel Primer	Accessory to device.	Surface device, intact skin, limited (<24h) duration.	Biocompatible. 510K cleared (K161654).

9.3. Conclusions from Safety, Performance and Bench Testing

The safety and performance testing results for EMC, Wireless Coexistence and bench testing concluded that the Trinity ELE Plus device meets and complies with the safety and performance of the applicable standards and bench testing requirements. These results and conclusions are described fully in detail in Sections 17 and 18 of this premarket notification.

The electrical safety tests for compliance to the ANSI AAMI 60601-1 and IEC 60601-1-11 standards are currently being conducted and will be provided to the FDA before the subject device is released to market.

9.4. Conclusions from Software Verification and Validation

The software verification and validation results concluded that the Trinity ELE Plus device meets and complies with the applicable software requirements specifications. These results and conclusions are described fully in detail in Sections 16 of this premarket notification.

10. Animal Testing

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

11. Clinical Testing

The substantial equivalence for the subject device will not be demonstrated by results of clinical testing. Therefore, no clinical testing was performed.

12. Substantial Equivalence

The Trinity ELE Plus device has the same intended use and indications for use as the predicate device. The subject device key technological characteristics are nearly identical to those of the predicate device.

The new Bluetooth Low Energy (BLE) wireless connectivity introduced in the subject device design is a widely used multi-industry-proven technology that augments the overall user experience. The results of EMC and Wireless Coexistence testing provided in this premarket notification demonstrate that the new Bluetooth wireless connectivity poses low risk to the user of the subject device.

During design and development, a Risk Analysis of the subject device was used to identify potential Hazards that could occur in use of the device, or in the event of Failure Modes of device components. The risk analysis also included those risks that could potentially be introduced by the addition of the new technological characteristics described above. The Risk Analysis was used to identify risk reduction measures which have been incorporated in the subject device design and labeling. As a result, the residual risks for the Trinity ELE Plus device are low.

13. 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 Trinity ELE Plus device is substantially equivalent to the predicate device.