January 22, 2021

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

Re: K201782
Trade/Device Name: NuFace Trinity Plus Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: December 2, 2020
Received: December 3, 2020

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)*
K201782

Device Name

NūFACE® Trinity Plus

Indications for Use *(Describe)*

The NūFACE® Trinity Plus Device is intended for facial and neck stimulation and is 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.

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

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: January 21, 2020

2. Subject Device Name

Device Trade / Proprietary Name:	NūFACE® Trinity Plus
Device Common or Usual Name:	NūFACE® Trinity Plus Facial and Neck 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:	K181008
Manufacturer:	Carol Cole Company dba NūFACE
Trade Name:	NūFACE® Trinity
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. Subject Device Description

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

The NūFACE® Trinity Plus is a hand-held device that produces low levels of microcurrent which is discharged through two dual-plated chrome spheres 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 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 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 spheres on the attachment head use chromium. The same chromium plating material and process is used in the predicate device chrome-plated spheres.

The subject device, including the attachment head, measures 5.20" H x 2.6" W x 1.6" D. The charging cradle measures 2.3" H x 3.0" W x 2.7" D.

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

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

5. Indications for Use

The NūFACE® Trinity Plus Device is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use.

6. Technological Characteristics

Item	Subject Device	Predicate Device	Same / Different
Anatomic Sites	Face and Neck	Face and Neck	Same
Type of Energy Output	Microcurrent	Microcurrent	Same
Energy Delivery	Microcurrent is delivered via dual chrome-plated spheres (optimized for contact with the skin)	Microcurrent is delivered via dual chrome-plated spheres (optimized for contact with the skin)	Same
Energy Flow	Microcurrent continuously alternates between the positive and negative spheres	Microcurrent continuously alternates between the positive and negative spheres	Same
Energy Output	User adjustable	User adjustable	Same
Microcurrent Boost	Yes, Temporary, User controllable	No	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

Special Requirements	Conductive Gel Primer	Conductive Gel Primer	Same
Wireless Technology	Bluetooth Low Energy (BLE)	None	Different
Output Frequency	Variable	Fixed	Different
Basic Unit Characteristics			
Power Source	Internal Rechargeable Lithium Ion Battery	Internal Rechargeable Lithium Ion Battery	Same
a. Method of Line Current Isolation	Type BF	Type BF	Same
b. Patient Leakage Current			---
1). Normal Condition	N/A - Battery operated	N/A - Battery operated	Same
2). Single Fault Condition	N/A - Battery operated	N/A - Battery operated	Same
External Power Adaptor	NuFACE 5-volt power adaptor	NuFACE 7-volt power adaptor	Similar
Number of Output Channels	1	1	Same
a. Synchronous or Alternating	N/A – 1 Output channel	N/A – 1 Output channel	Same
b. Method of Channel Isolation	N/A – 1 Output channel	N/A – 1 Output channel	Same
Regulated Current or Regulated Voltage	Both	Both	Same
Software/Firmware/ Microprocessor control	Yes	Yes	Same
Automatic Overload Trip	Not required due to circuit design	Not required due to circuit design	Same
Automatic No-Load trip	Yes	Yes	Same
Automatic Shut Off	Yes	Yes	Same
Patient Override Control	Yes	Yes	Same
Indicator Display			---
a. ON/OFF Status	Yes	Yes	Same
b. Low Battery	Yes	Yes	Same
c. Voltage Current Level	Yes	Yes	Same
Automatic Shut-off (Minutes)	Yes (20 minutes)	Yes (20 Minutes)	Same

Weight	8.8 oz. without charging base	9 oz. without charging base	Similar
Dimensions of Device (inch) [WxLxD]	2.6" x 5.20" x 1.6"	2.8" x 5.1" x 1.3"	Similar
Housing Materials and Construction	Thermoplastic	Thermoplastic	Same
Output Specifications			
Maximum Output Current Density	0.78 mA/cm2	0.419 mA/cm2	Different
Burst Mode (i.e. pulse trains)			---
a. Pulses per burst	20 (10 positive and 10 negative)	20 (10 positive and 10 negative)	Same
b. Pulses per second	8.3 (@ 8.3 Hz)	8.3	Same
c. Burst duration (seconds)	2.4s (@ 8.3 Hz)	2.4s	Same
d. Duty Cycle [Line (b) x Line (c)] (on time per burst)	Duty Cycle: 50% On time per burst: 20.2s	Duty Cycle: 50% On time per burst: 20.2s	Same?
On Time (seconds)	60 ms (@8.3 Hz)	60 ms	Same
Off Time (seconds)	60 ms (@8.3 Hz)	60 ms	Same

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 materials used in all patient-contacting parts is presented below.

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 complies to ISO 10993-1 "Biological evaluation of medical devices" ISO 10993-5: Tests for in vitro cytotoxicity, ISO 10993-10: Tests for irritation Intracutaneous; Skin sensitization; Cytotoxicity-Elution method.
Chromium	Plated over the two spheres 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).

7.3. Conclusions from Safety, Performance and Bench Testing

The safety and performance testing results for EMC, Electrical Safety, Wireless Coexistence and bench testing concluded that the NūFACE® Trinity 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 NūFACE® Trinity Plus device meets and complies with the applicable software requirements specifications.

8. Animal Testing

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

9. Clinical Testing

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

10. Substantial Equivalence

The NūFACE® Trinity 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 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.

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 NūFACE® Trinity Plus device are low.

11. Conclusion

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