February 19, 2021

Carole Cole Company
Bob Duffy
Regulatory Affairs Senior Manager
1325 Sycamore Ave, Suite A
Vista, California 92081

Re: K201680
Trade/Device Name: NuFACE Mini Plus
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: December 9, 2020
Received: December 10, 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)*
K201680

Device Name
NuFACE Mini Plus

Indications for Use *(Describe)*
The NūFACE® Mini 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.

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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 Information

Submitter:	Carol Cole Company dba NūFACE
Address:	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 17, 2021

2. Subject Device

510(k) Premarket Notification:	K201680
Device Trade / Proprietary Name:	NūFACE® Mini Plus
Device Common or Usual Name:	NūFACE® Mini 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

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

510(k) Number:	K191672
Manufacturer:	Carol Cole Company dba NūFACE
Trade Name:	NūFACE® Mini
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. Device Description

The NūFACE® Mini Plus (subject device) comprises the Mini Plus device itself and a wall-mount power adaptor. A tube of NūFACE® Gel Primer is provided with the device as an accessory. The Instructions for Use (IFU) are also included with the device. The device and all its associated components are reusable and provided non-sterile.

The subject device produces low levels of microcurrent that is discharged through two chrome-plated spheres when they come in contact with and are glided over the skin being treated.

The subject device allows the user to turn on and turn off the device at any time during the treatment. Once the device is on, the user can select different microcurrent intensity levels. The device provides visual (lights), audible (beeps) and haptic (hum) feedback to guide the user during treatment. The device will shut off automatically after 20 minutes of use.

The subject device is powered by one internal rechargeable, non-removable battery which is charged via the provided wall-mount power adaptor. During battery charging the device microcurrent output is disabled to prevent accidental and/or intentional use.

The subject device is capable of pairing and connecting to compatible smart devices using Bluetooth Low Energy (BLE) technology. BLE allows the subject device to wirelessly communicate with other devices such a smart phone running the NūFACE® App. The NūFACE® App allows the user to customize treatment options.

The subject device is made from thermoplastic and metal materials already used in other FDA-cleared medical devices. The device measures 2.7" W x 3.6" L x 2.6" D.

4.1. Intended Use

The Indications for Use statement for the subject device is identical to the predicate device.

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

5. Technological Characteristics

Table 1provides a comparison between the technological characteristics of the NūFACE® Mini Plus and the predicate device.

Table 1: Technological Characteristics

Item	Subject Device	Predicate Device	Same / Different
Type of Energy Output	Microcurrent	Microcurrent	Same
Energy Delivery	Microcurrent is delivered via plated dual sphere electrodes (optimized for contact with the skin)	Microcurrent is delivered via plated dual sphere electrodes (optimized for contact with the skin)	Same

Item	Subject Device	Predicate Device	Same / Different
Energy Flow	Microcurrent continuously alternates between the positive and negative electrode spheres	Microcurrent continuously alternates between the positive and negative electrode spheres	Same
Energy Output	User adjustable	User adjustable	Same
Energy Power Source	Internal rechargeable battery	Internal rechargeable battery	Same
Battery Type	Lithium Ion	Lithium Ion	Same
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	Conductive Gel Primer	Conductive Gel Primer	Same
Output Frequency (Hz)	Variable	Fixed	Different
Wireless Technologies	Bluetooth Low Energy (BLE)	None	Different

6. Performance Specifications Comparison

Table 2 provides a comparison between the performance specifications of the NūFACE® Mini Plus and the predicate device.

Table 2: Performance Specifications Comparison

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
Maximum Output Voltage	28 VDC	28 VDC	Same
Maximum Output Current	335 μA	348 μA	Same
Maximum Output Current Density	0.435 mA/cm^2	0.452 mA/cm^2	Same

Item	Subject Device Specification	Predicate Device Specification	Same / Different
Microcurrent Output (Device OFF / Not Stimulating	< 10 µA (device is OFF or Charging the battery)	< 1 µA (device is OFF or Charging the battery)	Different
Output Tolerance	+/- 5% (RMS)	+/- 5% (RMS)	Same
Pulse Period (Pulse Width)	Varies with Output Frequency	60 msec	Different
Output Frequency (Hz)	0.3 – 50 Hz (Variable)	Approximately 8.3 Hz	Different
Beat Frequency (Hz)	No Beat Frequency	No Beat Frequency	Same
Symmetrical Phases	Not Multiphasic	Not Multiphasic	Same
Phase Duration	Not Multiphasic	Not Multiphasic	Same
Net Charge (µC per pulse)	N/A - Battery operated	N/A - Battery operated	Same
Pulses Per Burst	20 (10 positive and 10 negative)	20 (10 positive and 10 negative)	Same
Pulses Per Second	Variable	8.3	Different
Burst Duration (sec)	Variable	2.4 sec	Different
Duty Cycle (DC)	50%	50%	Same
ON Time (msec)	Variable	60	Different
OFF Time (msec)	Variable	60	Different
Output Current Range	70 to 335 µA	35 to 348 µA	Same
Default Treatment Frequency (Hz)	Approximately 8.3 Hz	Approximately 8.3 Hz	Same

7. Non-Clinical Performance Data

A program of non-clinical verification and validation testing was conducted that includes:

- Biocompatibility
- Electrical Safety, EMC, and Performance Testing
- Software Verification and Validation Testing

7.1. Biocompatibility

Table 3 the conclusions drawn for each type of material used in the construction of the subject device and the accessories included with it. The metal and thermoplastic materials used in the NuFACE® Mini Plus are identical to materials already used in FDA-cleared devices in formulation, processing, sterilization, and geometry, and no other chemicals have been added. Biocompatibility is addressed in detail in a separate document in this premarket submission.

Table 3: NuFACE® Mini Plus Materials Biocompatibility

Material	**Where Used (Subject Device)**	**Categorization (ISO 10993-1)**	**Conclusion**
Metal	• Spheres.	Surface device, intact skin, limited contact duration (<24h).	Biocompatible. These materials are used in other FDA-cleared devices.
Thermoplastic	• Device Enclosure. • Grip Over-Mold. • Wall-Mount Power supply.	Surface device, intact skin, limited contact duration (<24h).	Biocompatible. These materials are used in other FDA-cleared devices.
Moisturizing Gel	• Conductivity Gel Primer.	Surface device, intact skin, limited contact duration (<24h).	Biocompatible. These materials are used in other FDA-cleared devices.

7.2. Electrical Safety, EMC, and Performance Testing

The following conclusions were drawn from the conducted Safety, Performance and Bench Testing:

1) Electrical Safety testing results demonstrated that the NūFACE® Mini Plus is compliant with applicable Standards for Electrical Safety.

2) Electromagnetic Compatibility (EMC) testing results demonstrated that the NūFACE® Mini Plus is compliant with applicable Standards for Electromagnetic Compatibility and Wireless Coexistence.

3) Performance Bench testing results demonstrated that the NūFACE® Mini Plus meets its performance specifications and is substantially equivalent to the predicate device performance.

7.3. Software Verification and Validation Testing

Software Verification and Validation Testing results demonstrated that:

1) All requirements and specifications in the NūFACE® Mini Plus Software Requirements Specification were implemented and operate correctly.

2) All Risk Mitigations to be implemented in software were implemented and operate correctly, and

3) the software conforms with the user needs and intended uses of the NūFACE® Mini Plus device.

7.4. Animal Testing

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

7.5. Clinical Testing

The substantial equivalence for the subject device is not demonstrated by results of clinical testing. Therefore, no clinical testing were performed.

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® Mini Plus is as safe, as effective, and performs as well as the predicate device.