DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 31, 2017

Carol Cole Company dba NuFACE
Donald Ellis
Regulatory Affairs / Quality Assurance Manager
1325 Sycamore Ave, Suite A
Vista, California 92081

Re: K171588
Trade/Device Name: NuBODY Skin Toning Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: May 31, 2017
Received: May 31, 2017

Dear Donald Ellis:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171588

Device Name
NuBODY Skin Toning Device

Indications for Use *(Describe)*
NuBODY Skin Toning Device is intended for body skin 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.

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NUFACE

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SECTION 5. 510(K) SUMMARY

DATE PREPARED: JULY 27, 2017

510(K) SUBMITTER/OWNER

Carol Cole Company
1325 Sycamore Ave, Suite A
Vista, CA 92081, USA

CONTACT INFORMATION:

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DEVICE NAMES

Device Trade/ Proprietary Name:	NuBODY Skin Toning Device
Device Common or Usual Name:	NuBODY
Classification Name:	stimulator, transcutaneous electrical, aesthetic purposes
Regulation Number:	21 CFR 882.5890
Product Code:	NFO

PREDICATE DEVICES

The legally marketed predicate device to which the Carol Cole Company is claiming equivalence for over-the-counter use:

510(k) Number:	K103472
Manufacturer:	Carol Cole Company dba NuFACE
Trade Name:	NuFACE® Plus
Product Code:	NFO

DEVICE DESCRIPTION

NuBODY Skin Toning Device is intended for body skin stimulation and is indicated for over-the-counter cosmetic use. Four (4) spherical electrodes, fixed on the NuBODY device main body, deliver low level electrical impulses (microcurrent) to targeted locations on the body.

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INTENDED USE

NuBODY Skin Toning Device is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.

TECHNOLOGICAL CHARACTERISTICS

The proposed NuBODY device has the same, or similar, technological characteristics as the NuFACE Plus predicate device. The differences do not alter the clinical utility of our proposed NuBODY device relative to the cleared NuFACE Plus predicate device listed below.

i) NuBODY device is powered by a rechargeable, nonreplaceable, battery which uses a lithium ion chemistry.

ii) Microcurrent is discharged through four (4) smooth, chrome-plated, spherical electrodes.

iii) Comparable to the NuFACE Plus predicate device, the NuBODY device generates continuous alternating microcurrent delivered in a burst of positive pulses followed by a burst of negative pulses.

PREDICATE COMPARISON

Table1: General Comparison Table

DEVICE DESCRIPTIONS	NUBODY (NEW DEVICE)	NUFACE PLUS DEVICE (PREDICATE)
1. 510(k) Number	K171588	K103472
2. Regulation Number	21 C.F.R. § 882.5890	21 C.F.R. § 882.5890
3. Regulation Name	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief
4. Regulatory Class	Class II	Class II
5. Device Classification Name	Stimulator, Transcutaneous Electrical, Aesthetic Purposes	Stimulator, Transcutaneous Electrical, Aesthetic Purposes
6. Product Code	NFO	NFO
7. Regulation Medical Specialty	Neurology	Neurology
8. Intended Use	NuBODY Skin Toning Device is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.	NuFACE Plus Facial Toning Device is intended for facial stimulation and is indicated for over the counter cosmetic use.
9. Indications for Use	Over-the-Counter Cosmetic Use	Over-the-Counter Cosmetic Use
10. Anatomic Sites	Areas of the body other than the face	Face
11. Technological Characteristics	The NuBODY Skin Toning Device is a body skin toning device. Its outer case is injection molded thermoplastic resin. The output contacts consist of chrome-plated spherical electrodes. The NuBODY device is powered by a rechargeable lithium ion battery. NuBODY device produces microcurrent that is discharged through four fixed, smooth spherical	The NuFACE Plus is a facial toning device. Its outer case is injection molded thermoplastic resin. The output contacts consist of chrome-plated spheres. The device is powered by a rechargeable lithium ion battery and produces a microcurrent that is discharged through two fixed, smooth electrode spheres. To turn the device on, the on/off

DEVICE DESCRIPTIONS	NUBODY (NEW DEVICE)	NUFACE PLUS DEVICE (PREDICATE)
	electrodes. To turn the NuBODY device on, the on/off button is pressed. Ascending tonal beeps indicate the NuBODY device is on. One to three LED lights illuminate indicating the output intensity level and the unit is ready for use. The four spheres gently glide over the skin to deliver low-level electrical impulses to targeted locations on the body. The NuBODY device spheres are designed for optimal contact with body skin. The NuBODY device delivers microcurrent as a constant monophasic square wave comprised of a burst of (10) positive pulses followed by a burst of (10) negative pulses. The microcurrent output continuously alternates between the positive and negative spherical electrodes, and allows the user to adjust the output for a personalized comfort level. The NuBODY device requires the use of a conductive gel. To promote proper use and provide feedback to the user, the NuBODY device beeps to cue the user to relocate the NuBODY device approximately every 5 seconds.	button is pressed. Ascending tonal beeps indicate the device is on. One to five red LED lights illuminate indicating the output intensity level and the unit is ready for use. Users then follow the instructions for use. The two spheres gently glide over the skin to deliver low-level electrical impulses to targeted locations on the face. The NuFACE Plus spheres are designed for optimal contact with the face. The NuFACE Plus device delivers microcurrent as a constant monophasic square wave comprised of a burst of (10) positive pulses followed by a burst of (10) negative pulses. The microcurrent output continuously alternates between the positive and negative electrode spheres, and allows the user to adjust the output for a personalized comfort level. The NuFACE Plus device requires the use of a conductive gel. To promote proper use and provide feedback to the user, the NuFACE Plus beeps to cue the user to relocate the device approximately every 5 seconds.

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Table 2: Basic Unit Characteristic Comparison

BASIC UNIT CHARACTERISTICS	NUBODY (NEW DEVICE)	NUFACE PLUS DEVICE (PREDICATE)
1. 510(k) Number	K171588	K103472
2. Device Name, Model	NuBODY Skin Toning Device	NuFACE Plus Facial Toning Device
3. Manufacturer	Carol Cole Company (dba NuFACE)	Carol Cole Company (dba NuFACE)
4. Power Source(s)	Internal rechargeable Lithium ion battery	Internal rechargeable Lithium ion battery
a. Method of Line Current Isolation	Type BF	Type BF
b. Patient Leakage Current		
1). Normal condition	N/A - Battery operated	N/A - Battery operated
2). Single fault condition	N/A - Battery operated	N/A - Battery operated
5. External power adapter	NuFACE 5-volt power adapter	NuFACE 7-volt power adapter
6. Number of Output Channels	1	1
a. Synchronous or Alternating	N/A - 1 Output channel	N/A - 1 Output channel
b. Method of Channel Isolation	N/A - 1 Output channel	N/A - 1 Output channel
7. Regulated Current or Regulated Voltage	Both	Both
8. Software/ Firmware/ Microprocessor Control	Yes	Yes
9. Automatic Overload Trip	Not required due to circuit design	Not required due to circuit design

BASIC UNIT CHARACTERISTICS	NUBODY (NEW DEVICE)	NUFACE PLUS DEVICE (PREDICATE)
10. Automatic No-Load Trip	Yes	Yes
11. Automatic Shut Off	Yes	Yes
12. Patient Override Control	Yes	Yes
13. Indicator Display		
a. On/Off Status	Yes	Yes
b. Low Battery	Yes	Yes
c. Voltage/Current Level	Yes	Yes
14. Automatic Shut-Off (minutes)	Yes (5 minutes)	Yes (20 minutes)
15. Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2 IEC 60529 IEC 60601-2-10 ISO 14971 IEC 60601-1-6 IEC 62366	IEC 60601-1 IEC 60601-1-2
16. Compliance with 21 CFR 898	Yes	Yes
17. Weight	Approximately 10-14 oz. without power adapter	9 oz. without charging base
18. Dimensions of device(inch) [W x L x D]	Approximately 2.75" x 6.5" x 6.0"	2.8" x 5.1" x 1.3"
19. Housing Materials and Construction	Thermoplastic	Thermoplastic

Table 3: Output Specification Comparison Table

OUTPUT SPECIFICATIONS	NUBODY (NEW DEVICE)	NUFACE PLUS DEVICE (PREDICATE)
1. 510(k) Number	K171588	K103472
2. Waveform (e.g., pulsed monophasic, biphasic)	Monophasic waveform that is delivered in a burst of pulses	Monophasic waveform that is delivered in a burst of pulses
3. Shape (e.g., rectangular, spike, rectified sinusoidal)	Voltage Modulated Square	Voltage Modulated Square
4. Maximum Output Voltage	28 VDC	28 VDC
5. Maximum Output Current	900 µA @ 500Ω	400 µA @ 500Ω
6. Maximum Output Current Density	0.468 mA/cm^2	0.419 mA/cm^2
7. Output Current when not stimulating	< 1 µA	< 1 µA
8. Output Tolerance	+/- 10%	+/- 10%
9. Pulse Width	60 ms	60 ms
10. Frequency (Hz)	Approximately 8.3 Hz	Approximately 8.3 Hz
11. For interferential modes, only		
a. Beat Frequency (Hz)	No Beat Frequency	No Beat Frequency
12. For multiphasic waveforms, only		
a. Symmetrical phases	Not Multiphasic	Not Multiphasic
b. Phase Duration (include units) c. (state range, if applicable) d. (both	Not Multiphasic	Not Multiphasic

OUTPUT SPECIFICATIONS	NUBODY (NEW DEVICE)	NUFACE PLUS DEVICE (PREDICATE)
phases, if asymmetrical)		
13. Net Charge (µC per pulse)	54 µC	24 µC
14. Burst Mode (i.e., pulse trains)		
a. Pulses per burst	20	20
b. Pulses per second	8.3	8.3
c. Burst duration (seconds)	2.4 s	2.4 s
d. Duty Cycle [Line (b) x Line (c)] (on time per burst)	20.2 s	20.2 s
15. ON Time (seconds)	60 msec	60 msec
16. OFF Time (seconds)	60 msec	60 msec
17. Maximum Average Power Density (mW/cm^2)	4.18	1.12
18. Maximum Phase Charge (mC/Burst)	1.08	0.48

BENCH TESTING

Nonclinical testing was performed to demonstrate that the NuBODY product met design specifications and is substantially equivalent to the NuFACE Plus predicate device. This performance testing was conducted using a production equivalent of the NuBODY, and a commercial unit of the predicate. The testing consisted of the evaluation of Output Waveform Characteristics and Output Energy Characteristics.

Additionally, Product Safety and EMC testing of the NuBODY was conducted in accordance with IEC 60601-1 and IEC 60601-1-2. The NuBODY device conformed to ANSI/AAMI ES60601-1: 2005 / A2:2010 for Electrical and

Constructional Safety and to IEC 60601-1-2 for Electromagnetic Compatibility (EMC) and IEC 60601-2-10.

All nonclinical test results for Output Waveform, Output Energy, Electrical and Constructional Safety and EMC confirm the NuBODY device is substantially equivalent to the NuFACE Plus predicate device.

CONCLUSION

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR part 807 and based on all relative information provided in this premarket notification, we conclude the NuBODY Skin Toning Device is substantially equivalent to the NuFACE Plus predicate device with regards to safety and effectiveness.