DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 30, 2016

Carol Cole Company
Merle Kovacic
Regulatory Affairs/Quality Assurance Specialist
1325 Sycamore Avenue, Suite A
Vista, California 92081

Re: K161654
Trade/Device Name: NuFACE Gel Primer
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: December 5, 2016
Received: December 7, 2016

Dear Merle Kovacic:

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)*
K161654

Device Name
NuFACE Gel Primer

Indications for Use *(Describe)*
The NuFACE Gel Primer is intended to be used with NuFACE microcurrent devices to improve skin conductivity.

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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SECTION 5. 510(K) SUMMARY

Date Prepared: May 28, 2016

510(k) Submitter/Owner

Carol Cole Company dba NuFACE®

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Contact Information:

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Device Names

Device Trade/ Proprietary Name:	NuFACE® Gel Primer
Device Common or Usual Name:	Electroconductive gel
Classification Name:	Media, Electroconductive
Regulation Number:	21 CFR 882.1275
Product Code:	GYB

Predicate Device

The legally marketed device to which NuFACE® claims substantial equivalence is the Prizm Medical, Inc. Thera-Cream™.

510(k) Number:	K032239
Manufacturer:	Prizm Medical, Inc.
Trade Name:	Thera-Cream
Product Code:	GYB

Device Description

The NuFACE Gel Primer is a clear, viscous and chloride-free formulation. The gel is to be applied to the area under an electrode to reduce the impedance of the contact interface between the electrode surface and the skin.

Intended Use

The NuFACE Gel Primer is intended to be used with NuFACE microcurrent devices to improve skin conductivity.

Technological Characteristics

The key technological characteristics of the NuFACE Gel Primer are:

1. conductivity
2. biocompatibility, and
3. viscosity
4. pH

The NuFACE Gel Primer is biocompatible for surface contact with intact skin, and therefore complies with:

a. ISO 10993-5 for *in vitro* Cytotoxicity
b. ISO 10993-10 for Skin Sensitization
c. ISO 10993-10 for Skin Irritation

The proposed device is formulated with a viscosity which permits the microcurrent device to easily glide across the skin for optimum results. It is a nonsterile topical gel applied to intact skin.

Predicate Comparison

As shown below in Table 1, the NuFACE Gel Primer is substantially equivalent to the predicate device in safety and effectiveness.

Table 1 Predicate Device Comparison

Items	NuFACE Gel Primer (Proposed Device)	Thera-Cream (Proposed Predicate)	Substantial Equivalence Comments
510(k) No.	K161654	K032239	N/A
Intended Use	The NuFACE Gel Primer is intended to be used with NuFACE microcurrent devices to improve skin conductivity.	Thera-Cream is a conductive cream, which increases skin conductivity for electrotherapy treatment and was developed for use with the Prizm brand electrotherapy units and the Intelligent Textiles brand of garment electrodes.	Equivalent to predicate
Environment of Use	Home	Home	Same as predicate
Intended User	Adults 18 years of age or older	Adults	Equivalent to Predicate
Where Used	Topically on intact skin	Topically on intact skin	Same as predicate
Conductive Material	Salt (Magnesium Sulfate)	Conductive Copper Salts	Equivalent to Predicate
Sterilization	Non-sterile	Non-sterile	Same as predicate
Biocompatibility	Complies with ISO 10993-1, ISO 10993-5, and ISO 10993-10	Complies with ISO 10993-1, ISO 10993-5, and ISO 10993-10	Same as predicate
Chemical Safety	Non-OSHA PEL	Non-OSHA PEL	Same as predicate
Volume or Weight	2 fl. oz. and 5 fl. oz. tube	4.2 fl. oz. tube	Equivalent to Predicate

Performance Testing

The NuFACE Gel Primer was tested for the following characteristics:

1. Physical, chemical and biological characteristics including color, odor, appearance, pH, microbiological growth, specific gravity and viscosity;
2. Conductivity;
3. Biocompatibility;
4. Packaging compatibility; and
5. Stability.

The test results demonstrate that the NuFACE Gel Primer meets the established specifications.

Biocompatibility Evaluation

The biocompatibility of the NuFACE Gel Primer was evaluated in accordance with ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. The representative samples of the gel were tested for cytotoxicity (ISO 10993-5), skin irritation and skin sensitization (ISO 10993-10). All testing was performed in accordance with CFR 21 Part 58 Good Laboratory Practice (GLP). The test results demonstrate the NuFACE Gel Primer is biocompatible when used as intended.

Conclusion

Based on the results of the performance tests and the biocompatibility evaluation, NuFACE Gel Primer is substantially equivalent to the predicate device in safety.