June 27, 2024

Carol Cole Company dba NuFACE®
Robert Castro
Director of Quality and Regulatory
1325 Sycamore Ave
Suite A
Vista, California 92081

Re: K240564
Trade/Device Name: NuFACE® FIX+
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: April 15, 2024
Received: April 16, 2024

Dear Robert Castro:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240564

Device Name

NuFACE® FIX+

Indications for Use *(Describe)*

The NuFACE FIX+ Device is intended for facial 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
NūFACE® FIX+

1. SUBMITTER

Submitter:	Carol Cole Company dba NūFACE®
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Email:	rcastro@nuface.com
Contact Person:	Robert C. Castro
Date Prepared:	April 15, 2024

2. DEVICE

Name of Device:	NūFACE® FIX+
Common or Usual Name:	FIX+
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Regulation Number:	21 CFR 882.5890
Regulatory Class:	Class II
Product Code:	NFO

3. PREDICATE DEVICE

Name of Device:	NūFACE® FIX Skin Toning Device
510(k) Number:	K182424 This predicate device has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

- FIX+ is a portable hand-held microcurrent stimulator for facial skin stimulation indicated for over-the-counter cosmetic use.
- Main components: Main unit, USB power cable, and NuFACE Line Smoothing FIX Serum conductivity gel.
- Housing of the device made from Acrylonitrile Butadiene Styrene, with chrome-plated spherical probes.
- Inclusion of three microcurrent output frequency levels.
- Integrated rechargeable lithium-ion battery

5. INTENDED USE

The NuFACE® FIX+ Device is intended for facial stimulation.

6. INDICATIONS FOR USE

The NuFACE FIX+ Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.

7. DEVICE COMPONENTS

The following materials are expected to contact the user in normal use:

Device Component	Composition
Two (x2) Spheres	Chromium plating
Handheld Unit Enclosure	Acrylonitrile Butadiene Styrene (ABS).

8. ACCESSORIES

Accessories	Description
FIX+ device	NūFACE® FIX+
Power Cord	USB-to-DC Power cable (Charge only)
Conductivity Gel	NūFACE® Line Smoothing FIX Serum Sizes: 2 fl. oz. or 5 fl. oz. To be applied before treatments

9. DESIGN AND TECHNOLOGICAL SPECIFICATIONS

FIX+ is based on the design of the established NūFACE® FIX Skin Toning Device (predicate device - K182424). The primary distinction from the predicate device involves a slight modification in the shape and dimensions of the device housing, the inclusion of three (3) adjustable microcurrent output frequencies, and an increased microcurrent output intensity.

10. TECHNOLOGICAL CHARACTERISTICS COMPARISON

Technological Characteristics Comparison		
Category	**NuFACE FIX+ (SUBJECT DEVICE)**	**NuFACE FIX Line Smoothing Device (PREDICATE)**
Type of Energy Output	Microcurrent	Microcurrent
Energy Delivery	Microcurrent is delivered via two fixed, smooth spherical electrodes	Microcurrent is delivered via two fixed, smooth spherical electrodes
Energy Flow	Microcurrent continuously alternates between the positive and negative electrode spheres	Microcurrent continuously alternates between the positive and negative electrode spheres
Energy Output	Constant biphasic square wave	Constant biphasic square wave
Energy Power Source	Internal rechargeable battery	Internal rechargeable battery
Battery Type	Lithium Ion	Lithium Ion
Charging Circuitry	Internal to Device	Internal to Device
Charging Method	USB Power Cable	USB Power Cable
Waveform	Pulsed Biphasic	Pulsed Biphasic
Shape	Modulated Square	Modulated Square
Maximum Output Voltage	28 VDC	28 VDC
Software	Yes	Yes
Firmware	Yes	Yes

Technological Characteristics Comparison		
Category	**NuFACE FIX+ (SUBJECT DEVICE)**	**NuFACE FIX Line Smoothing Device (PREDICATE)**
Microprocessor Control	Yes	Yes
Output Frequency	Variable frequency ranging from 8.3 Hz to 50.0 Hz	Approximately 8.3 Hz
Range of Output Frequency (Hz)	Range of 2-50 Hz	8.3 Hz
Wireless Technologies	None	None
Wireless Capability	None	None
Output Intensity (µA)	225 µA	200 µA
Maximum Output Current Density	0.480 mA/cm2	0.418 mA/cm2

Table 4: Performance Specifications Comparison		
Category	NuFACE FIX+ (Subject Device)	NuFACE FIX Line Smoothing Device (Predicate)
Maximum Output Current	225 µA @ 10000Ω	208 µA @ 500Ω
Output Current when not stimulating	< 1 µA	< 1 µA
Output Tolerance	+/- 10%	+/- 10%
Pulse Width	10 – 60 ms	60 ms

Table 4: Performance Specifications Comparison		
Category	NuFACE FIX+ (Subject Device)	NuFACE FIX Line Smoothing Device (Predicate)
Frequency (Hz)	Range of 8.3 - 50 Hz	Approximately 8.3 Hz
Symmetrical phases	Biphasic	Biphasic
Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Biphasic	Biphasic
Net Charge (µC per pulse)	0	0
Burst Mode (i.e., pulse trains)		
a. Pulse ON time (msec)	10ms to 60ms	60
b. Pulse OFF time (msec)	10ms to 60ms	60
c. Pulses per burst	20	20
d. Pulses per second	8.3 to 50	8.3
e. Burst duration (sec)	0.4 to 2.4	2.4
f. Duty Cycle	50%	50%

Technological Comparison Conclusion
The NūFACE® FIX+ maintains core technological similarities with the predicate NūFACE® FIX Line Smoothing Device, including microcurrent energy output and delivery. The expanded frequency range and increased microcurrent output intensity represent technological enhancements that offer additional features for the user, but do not impact the device's intended clinical use for cosmetic facial stimulation.

11. TESTING SUMMARIES

a. Safety Testing

NūFACE® FIX+ device was tested and has demonstrated compliance with applicable IEC standards concerning electrical safety and EMC.

Electrical, Mechanical, and Thermal Safety Testing were conducted according to the following standards:

IEC 60529	Ingress Protection
IEC 60601-1	Basic safety and essential performance (Electrical Equipment)
IEC 60601-1-11	Basic safety and essential performance (Med Dev Home Use)
IEC 60601-1-2	EMC - Basic safety and essential performance (Electromagnetic Disturbances)
IEC 60601-1-6	Basic safety and essential performance (Med Dev Electrical Equipment)
IEC 60601-2-10	Basic safety and essential performance (Med Dev Home Use – nerve and muscle stimulators)
ISO 10993-1	Biological Evaluation of Medical Devices
ISO 14971	Risk Management (Med Dev)
TR 60601-4-2	Medical Electrical Equipment
IEC 62366	Usability engineering (Med Dev)

b. Common EM Emitters

The FIX+ was tested to all applicable clauses of the IEC 60601-1-2: Edition 4.1, IEC 60601-4-2 Edition 1.0, and IEC 55014-2:2021 standards. In addition, a Common Emitter evaluation, for some of the most common electromagnetic emitters a home user could encounter, was conducted per FDA guidance document “Electromagnetic Compatibility (EMC) of Medical Devices” (06/06/2022). A Common Emitter evaluation is provided with this submission.

c. Bench Testing

Extensive bench testing was conducted to ensure the output waveform characteristics and the microcurrent output performance levels met the established product requirements within the designed tolerances. These tests are addressed in detail in the Performance Testing Section of this premarket notification.

Performance bench testing was conducted using production equivalent devices of the NūFACE® FIX Plus device. The testing was comprised of:

- Output Waveform Characteristics
- Output Energy Characteristics

Subsequent to performance bench testing, FIX+ production equivalent devices were also tested by a third-party accredited laboratory (Nemko USA) in accordance with IEC 60601-2-10 Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

Both internal performance bench testing and laboratory testing conducted concluded that the subject FIX+ device waveform and energy characteristics fall within their intended specifications and are substantially equivalent to the predicate device.

d. Software Verification and Validation Testing

Certification and validation testing for the subject device were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Details are provided in the Software Verification Section of this premarket notification.

Testing requirements were determined by the FIX+ Design Inputs & PRD and complemented with compliance testing performed at Nemko USA. All test requirements are considered as Passed and the user interface features, functions, and output of the FIX+ devices meet the specified design input criteria.

e. Animal Study and Clinical Studies

The provided documentation asserts that the determination of substantial equivalence for the device in question will not involve animal or clinical studies; hence, no such studies have been conducted to support this claim. Instead, a comparison of performance specifications with a predicate device will be used for the assessment.

f. Biocompatibility

NuFACE products classified as medical devices are subject to a Biocompatibility Evaluation per the FDA's guidance document titled "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process. The FIX+ device is categorized as a surface device which makes repeated contact with intact skin. Since this device can be used up to 2 times per treatment area and 5 days per week for the lifetime of the product, the device has long-term (>30 day) repeated contact with human tissue. Biocompatibility evaluation endpoints were assessed in accordance with the "Evaluation of Endpoints for Consideration" detailed in Attachment A of the FDA's guidance document titled "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process." The FIX+ device was evaluated for Biocompatibility as a Surface Device with contact with intact skin with a long-term contact duration of greater than 30 days.

12. CONCLUSION

The NūFACE® FIX+ is found to be substantially equivalent to its predicate, the NūFACE® FIX Line Smoothing Device (K182424). This determination is based on the similarity in intended use, indications for use, and the majority of the technological characteristics between the two devices. Although there are some differences in output characteristics like pulse width and frequency range, these do not affect the devices' clinical efficacy or intended cosmetic functions. The detailed analysis provided in the Substantial Equivalence Section of the premarket notification confirms that the observed technological differences do not introduce new safety and effectiveness concerns.