DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 24, 2017

ZIIP, LLC
David Mason
Co-Founder
1871 Trestle Glen Rd
Piedmont, California 94610

Re: K161484
Trade/Device Name: ZIIP Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: January 16, 2017
Received: January 24, 2017

Dear Mr. Mason:

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 yours,

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)*
Kl61484

Device Name
ZIIP Device

Indications for Use *(Describe)*
The ZIIP 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.

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

510(k) Notification K161484

GENERAL INFORMATION

Applicant (§807.92(a)(1)) :
ZIIP LLC
182 Howard St. #151
San Francisco, CA 94105
Telephone: 1-800-944-7031

Contact Person (§807.92(a)(1)):
David Mason
Co-Founder
ZIIP, LLC
david@ziipbeauty.com

Date Prepared (§807.92(a)(1)):
May 17, 2016

DEVICE INFORMATION

Trade Name (§807.92(a)(2)):
ZIIP Device

Generic/Common Name (§807.92(a)(2)):
Facial Toning Device

Classification (§807.92(a)(2)):
Transcutaneous Electrical Nerve Stimulator – CFR 882.5890

Product Code:
NFO

PREDICATE DEVICE(S) (§807.92(a)(3))

- K103472 - NuFace Plus Facial Toning Device

DEVICE DESCRIPTION (§807.92(a)(4))

The ZIIP Device is a hand-held, battery-powered device used with conductive gel to stimulate the face superficially through application of transcutaneous electrical currents. It is intended to be used by a single user (*multiple applications*).

INDICATIONS FOR USE/INTENDED USE (§807.92(a)(5))

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

TECHNOLOGICAL CHARACTERISTICS/PRINCIPLES OF OPERATION (§807.92(a)(6))

The ZIIP Device is a Facial Toning Device intended for facial stimulation. It produces a small electrical current discharged through the two electrodes. The current delivered is an aesthetic modality providing a small electric current in millionths of an ampere and has the ability to increase facial contour and firm the skin and muscles by supplying a maximum of +/- 200 micro amperes of current. The device measures 2.00" W x 3.9" L x 1.40" D (fits in the palm of a hand) and weighs 3.2 ounces. The outer case of the ZIIP Device is manufactured using injection-molded of thermoplastic resin and the output contacts (probes) consist of chrome-plated spheres. The device is powered by Lithium-Ion rechargeable batteries (*3.7V, 700mAh* (*503048-2C) / 2.59Wh, 1.4A rate*). The ZIIP Device is shipped with a portable batter-charger (*Charging Rate: 0.7A Max. 1.0C rate*).

The ZIIP Device was designed with an easy-to-use, ergonomic user interface that has one button to power the device on and off, curved design, and protruding chrome-plated electrodes for ease of facial application. The device is turned on by momentarily pressing the ON/OFF button once. The device annunciates its being turned on by beeping once, flashing a light indicator, and by a single haptic vibration. The device may be turned off at any time by pressing the ON/OFF button once. The device annunciates its being turned off by beeping twice. The unit turns-off if the battery voltage drops below 3.4 Volts.

The ZIIP Device spherical probes are designed for optimal contact with the face. The white LEDs turn-on if the unit can sense 100 nA or greater of electrode current. There is no specific skin impedance at which this happens. The device requires the use of a conductive gel. The conductive gel is used to reduce the impedance between the electrodes and the skin of the user.

Waveform Description

The ZIIP Device provides one continuous waveform output type, a square wave. For duty cycle, the ZIIP device has a 100% duty cycle because the user is receiving energy on both the positive and negative portions of the square waves at the electrodes. This then translates to the values for "maximum current density" and "maximum power density" which are premised on the calculated value of the peak current in use.

SUBSTANTIAL EQUIVALENCE DISCUSSION & SUMMARY OF COMPARISON DATA (§807.92(a)(6)(a)(b))

The ZIIP device has the same intended use and indications for use as the claimed predicate device. The device also has similar technological characteristics. During the design and development, risk management tools were employed in accordance with ISO 14971 (*Medical devices — Application of risk management to medical devices*) requirements. The risk assessment for the ZIIP Device was used to identify potential hazards that could occur during the use of the device, or in the event of failure modes associated with device components. Risk analysis was used to identify risk reduction measures which have been incorporated in the device design and labeling.

Device Descriptions - Comparison ZIIP Device with Predicate (§807.92(a)(6)(a)(b))

Basic Unit Characteristics	ZIIP Device	NuFace® Plus
510(k) Number	K161484	K103472
Regulation Number	21 CFR, Part 882.5890	21 CFR, Part 882.5890
Regulation Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator
Regulation Class	Class II	Class II
Product Code	NFO	NFO
Intended Use	Stimulate the Face – Skin Toning	Stimulate the Face – Skin Toning
Indications for Use	Over-the-counter cosmetic use	Over-the-counter cosmetic use
Technological Characteristics	The ZIIP Device is a Facial Toning Device intended for facial stimulation. It produces a small electrical current discharged through the two electrodes. The current delivered is an aesthetic modality providing a small electric current in millionths of an ampere and has the ability to increase facial contour and firm the skin and muscles by supplying a maximum of +/- 200 micro amperes of current. The device measures 2.00" W x 3.9" L x 1.40" D (fits in the palm of a hand) and weighs 3.2 ounces. The outer case of the ZIIP Device is manufactured using injection-molded of thermoplastic resin and the output contacts (probes) consist of chrome-plated spheres. The device is powered by Lithium-Ion rechargeable batteries (*3.7V, 700mAh* (*503048-2C) / 2.59Wh, 1.4A rate*). The ZIIP Device is	The Nu-Face Plus is a Facial Toning Device intended for facial stimulation. It produces a micro-current discharged through the two spherical probes. Micro-current is an aesthetic modality providing electric current in millionths of an ampere and has the ability to increase facial contour and firm the skin and muscles by supplying 80 - 400 pA. The device measures 3" W x 5.25' L x 1.25' D. Its outer case is injection molded of thermoplastic resin and the output contacts (probes) consist of chrome-plated spheres. The device is powered by 4 rechargeable batteries. The NOFACE® Plus comes with a rechargeable base, which measures 3.25" W x 4" L x 3.25" D.

	shipped with a portable batter-charger (*Charging Rate: 0.7A Max. 1.0C rate*).	

Basic Unit & Output Characteristics (§807.92(a)(6)(a)(b))

Basic Unit Characteristics	ZIIP Device	NuFace® Plus
510(k) Number	K161484	K103472
Device Name & Model	ZIIP Device	NuFace® Plus
Manufacturer	ZIIP, LLC	Carol Cole Company
Regulation Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator
Power Source(s)		
a. Method of Line Current Isolation	One Rechargeable Lithium-Ion Battery, and External Charger Isolation	4 rechargeable AA NiMH batteries
b. Patient Leakage Current	(External Charger Included)	
1. Normal Condition	46uA	N/A – Battery Operated
2. Single Fault Condition	46uA	N/A – Battery Operated
Number of Output Modules	N/A	1
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
Regulated Current or Regulated Voltage	Both	Both
Software/Firmware/Microprocessor Controlled	Yes	Yes
Automatic Overload Trip	Not required because of circuit design (Current and Voltage Limited by Circuit Design and Firmware)	Not required because of circuit design
Automatic No-Load Trip	Yes (Reversion to Fixed Voltage Output)	Yes
Automatic Shut Off	Yes	Yes
Patient Override Control	Yes	Yes
Indicator Display		
a. On/Off Status	Yes (LED Illumination on Conduction)	Yes
b. Low Battery	Yes	Yes
c. Voltage/Current Level	Yes (LED Illumination on Target Current Levels)	Yes
Timer Range	Yes	Yes (21-Minutes)

Basic Unit Characteristics	ZIIP Device	NuFace® Plus
Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
Weight	3.2 oz	9 oz
Dimensions	2" X 3.9" X 1.4"	3" x 5.2" x 1.25"
Housing Material Construction	Thermo Plastic	Thermo Plastic
Electro-conductive Material required?	Conductive Gel (§882.1275)	NuFACE Primer

Waveform/Output Comparison (§807.92(a)(6)(a)(b))

Basic Unit Characteristics	ZIIP Device	NuFace® Plus
Waveform	Pulsed Biphasic	Pulsed Monophasic
Shape	Modulated Square Wave	Modulated Square Wave
Maximum Output Voltage	154mV@ 500Ω	137mV @ 500Ω
	465mV@ 2KΩ	769mV @ 2KΩ
	2.2V @ 10KΩ	3.82V @ 10KΩ
Maximum Output Current	308µA @ 500Ω	274µA @ 500Ω
	232uA @ 2KΩ	387µA @ 2KΩ
	202µA @ 10KΩ	383µA @ 10KΩ
Output Tolerance	+/- 10%	+/- 2%
Pulse Width	50µs	119ms
Frequency	50.0Hz	8.4Hz
For Interferential Modes Only		
Beat Frequency	No Beat Frequency	No Beat Frequency
For Multiphasic Waveforms		
Symmetric Phases?	Multiphasic	Not Multiphasic
Phase Duration	10.0ms Positive/10.0ms Negative	Not Determined
Net Charge(μC per pulse)	N/A – Battery Operated	N/A – Battery Operated
On Time (Seconds)	Constant	Constant
Off Time (Seconds)	None	None
Maximum Phase Charge (µC)	6.16µC @ 500Ω	23.06µC @ 500Ω
Maximum Current Density (mA/cm^2)	0.034mA/cm^2 @ 500Ω	0.419mA/cm^2 @ 500Ω
Maximum Power Density (µW/cm^2)	3.44uW/cm^2@ 500Ω	3.22µW/cm^2 @ 500Ω

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION (§807.92(a)(6)(b)(1)

The ZIIP Device was tested and found to be in compliance with FDA's performance standards in accordance with 21 CDR, Part 898 (*Performance Standards for Electrode Lead Wires and Patient Cables*). Additionally, the ZIIP Device was tested and found to be in compliance with IEC 60601-1 -2 (*Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – requirements and tests*) for radiated and power line conducted emissions. Furthermore, the ZIIP Device was evaluated and found to be in compliance with lEC 60601-1 (*Medical electrical equipment: Part 1: General requirements for basic safety and essential* performance) for Electrical Safety. Finally, the ZIIP Device has been tested to demonstrate its performance specifications are equivalent to

the NuFace Plus, and has been validated in accordance with IEC 60601-1 and IEC 60601-1-2 requirements. *Note: the materials that come in contact with the user skin have been assessed in accordance with ISO 10993 (Biological evaluation of medical devices package).*

LIST OF NONCLINICAL SAFETY TESTS PERFORMED

Table below delineates the compilation of nonclinical testing employed for the testing of the ZIIP Device.

Non-clinical Testing Employed

Test	Name	Testing Facility	Results
IEC 60601-1	Medical electrical equipment: Part 1: General requirements for basic safety and essential performance	ITC Engineering services	Pass
IEC 60601-1-2	*Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – requirements and tests*	ITC Engineering	Pass

Product Testing

The ZIIP Device was thoroughly tested during design verification testing and design validation testing. A brief summary has been placed into the table above. Additionally, performance testing was performed in accordance with IEC 60601-1-2:2007, Medical Electrical Equipment.

Compilation of Test Protocols & Reports

Protocol & Report Number	Title	Date	Results
199001-005, Rev 0	ZiiP 1.00 Validation Plan and Protocol	2/28/16	N/A
199001-006, Rev 0	ZiiP 1.00 Validation Report	2/28/16	Pass
199001-007, Rev 0	ZiiP 1.00 Verification Plan and Protocol	2/28/16	N/A
199001-008, Rev 0	ZiiP 1.00 Verification Report	2/28/16	Pass

CLINICAL TESTING (§807.92(a)(6)(b)(2)

There was no clinical testing performed in support of this 510(k) submission.

CONCLUSION (§807.92(a)(6)(b)(3)

The ZIIP Device is substantially equivalent to the predicate device identified in this summary and previously cleared by FDA in accordance with 21 CFR, Part 807 requirements.