September 23, 2021

ZIIP, Inc.
% Heather Tanner
Principle Consultant
Hill Regulatory Consulting, LLC
1910 15th Ave E
Seattle, Washington 98112

Re: K212342
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: July 23, 2021
Received: July 28, 2021

Dear Heather Tanner:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212342

Device Name
ZIIP+ Device

Indications for Use *(Describe)*
The ZIIP+ Device is indicated 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.

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510(k) SUMMARY

510(k) Notification K212342

1. GENERAL INFORMATION

Applicant:
ZIIP Inc.
1425 Leimert Blvd
Suite 203
Oakland, CA 94602

Contact Person:
David Mason
President, ZIIP, Inc.
Contact information: david@ziipbeauty.com

Date Prepared:
July 23, 2021

2. DEVICE INFORMATION

Trade Name:
ZIIP+ Device

Generic/Common Name:
Facial Toning Device

Classification:
Transcutaneous Electrical Nerve Stimulatory – CFR 882.5890

Product Code:
NFO

3. PREDICATE DEVICE(S)

- K161484 – ZIIP Skincare Device
- K201782 - NūFACE® Trinity Plus

4. INDICATIONS FOR USE

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

5. DEVICE DESCRIPTION

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. The device is powered by a Lithium-Ion rechargeable battery, and it is shipped with a portable battery charger.

6. SUBSTANTIAL EQUIVALENCE

The ZIIP+ is substantially equivalent to the legally marketed ZIIP device (K161484) and the NuFACE Trinity Plus Device (K201782). The ZIIP+ Device has the identical output characteristics, principles of operation, and treatment method, and it has a similar indication for use as the predicate ZIIP Device. In addition, the ZIIP+ Device has the same intended use and indication for use [facial and neck toning] as the NuFACE Trinity Plus Device, as well as substantially equivalent technological characteristics and principles as operation, including Bluetooth Low Energy (BLE) capability.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

General Device Characteristics

	ZIIP+ Subject Device	ZIIP Predicate Device	NuFace Trinity Plus Predicate Device
Manufacturer	ZIIP Inc.	ZIIP Inc.	NuFace
K Number	K212342	K161484	K201782
Device Name	ZIIP+	ZIIP	NuFace Trinity Plus
OTC/Rx	OTC	OTC	OTC
Med Dev Class	Class II	Class II	Class II
Product Code	NFO	NFO	NFO
Common Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator
Mechanism of Action	Microcurrent electrical therapy to deliver skin stimulation through cellular response	Microcurrent electrical therapy to deliver skin stimulation through cellular response	Microcurrent electrical therapy to deliver skin stimulation through cellular response
Device Type	21 CFR, Part 882.5890	21 CFR, Part 882.5890	21 CFR, Part 882.5890
Indications for Use /Intended Use	The ZIIP+ Device is intended for facial and neck stimulation and is indicated for over-the-counter use.	The ZIIP Device is intended for facial stimulation and is indicated for over-the-counter use.	The NuFace Trinity Plus Device is intended for facial and neck stimulation and is indicated for over-the-counter use.
Material/ Biocompatibility	Biocompatible materials typically used in medical devices and identical to predicate ZIIP device	Biocompatible materials typically used in medical devices.	Biocompatible materials typically used in medical devices.
Power source	Internal Rechargeable Lithium Ion Battery	Internal Rechargeable Lithium Ion Battery	Internal Rechargeable Lithium Ion Battery
Performance standard	No known required performance standards	No known required performance standards	No known required performance standards
Sterility	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile

Human Factors	Ergonomic handheld design	Ergonomic handheld design	Ergonomic handheld design
Electrical Safety	Compliant with IEC 60601-1, 60601-1-2, 60601-1-11	Compliant with IEC 60601-1, 60601-1-2	IEC 60601-1, 60601-1-2, 60601-1-11
Type of Energy	Electrical current	Electrical current	Electrical current
Charging Method	External wall adaptor	External wall adaptor	Wireless charging
Charging Circuitry	Internal to device	Internal to device	Internal to device
Special Requirements	Conductive gel	Conductive gel	Conductive gel primer
Wireless Capability	Bluetooth Low Energy (BLE)	N/A	Bluetooth Low Energy (BLE)

Detailed Output Characteristics

Detailed Output Specifications	**ZIIP Subject Device**	**ZIIP Predicate Device**	**NuFace Trinity Plus**
Power Source(s)			
a) Method of Line Current Isolation	One rechargeable Lithium-Ion Battery and External Charger Isolation	One rechargeable Lithium-Ion Battery and External Charger Isolation	One rechargeable Lithium-Ion Battery and External Charger Isolation
b) Patient Leakage Current	External Charger Included	External Charger Included	External Charger Included
1. Normal Condition	46 μA	46 μA	N/A – Battery Operated
2. Fault Condition	46 μA	46 μA	N/A – Battery Operated
Number of Output Modules	1	1	1
Number of Output Channels	1	1	1
a) Synchronous or Alternating	N/A – 1 Output Channel	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	N/A – 1 Output Channel
Regulated Current or Regulated Voltage	Both	Both	Both
Software/ Firmware/ Microprocessor Controlled	Yes	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 (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 (Reversion to Fixed Voltage Output)	Yes
Automatic Shut Off	Yes	Yes	Yes
Patient Override Control	Yes	Yes	Yes
Indicator Display			
a) On/Off Status	Yes (LED Illumination on Conduction)	Yes (LED Illumination on Conduction)	Yes
b) Low Battery	Yes	Yes	Yes
c) Voltage/Current Level	Yes (LED Illumination on Target Current Levels)	Yes (LED Illumination on Target Current Levels)	Yes

Output Specifications	ZIIP Subject Device	ZIIP Predicate Device	NuFace Trinity Plus
Waveform	Pulsed Biphasic	Pulsed Biphasic	Pulsed Monophasic
Shape	Modulated Square Wave	Modulated Square Wave	Modulated Square Wave
Maximum Output Voltage	154mV@500Ω 465mV@52KΩ 2.2V@10KΩ	154mV@500Ω 465mV@52KΩ 2.2V@10KΩ	Not publicly available
Maximum Output Current	309μA@500Ω 232μA@2KΩ 202μA@10KΩ	309μA@500Ω 232μA@2KΩ 202μA@10KΩ	Not publicly available
Burst Mode (i.e. pulse trains)			
Pulses per burst	N/A – no burst mode	N/A – no burst mode	20 (10 positive and 10 negative)
Pulses per second			8.3 (@ 8.3 Hz)
Burst duration (seconds)			2.4s (@ 8.3 Hz)
Duty Cycle [Line (b) x Line (c)] (on time per burst)			Duty Cycle: 50% On time per burst: 20.2s
On time (seconds)	Constant	Constant	60 ms (@8.3 Hz)
Off time (seconds)	None	None	60 ms (@8.3 Hz)
Maximum Phase Charge (μC)	6.16 μC@500Ω	6.16 μC@500Ω	23.06 μC@500Ω
Maximum Current Density (mA/cm^2)	0.34 mA/cm2 @500Ω	0.34 mA/cm2 @500Ω	0.78 mA/cm2 @500Ω
Maximum Power Density (μW/cm^2)	3.44 W/cm2@500Ω	3.44 W/cm2@500Ω	3.22 μW/cm2@500Ω

8. NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Comprehensive performance testing was performed to support the substantial equivalence determination for the ZIIP+ Device, including the following:

- Electrical Safety Testing, including EMC. Specifically, 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
  - lEC 60601-1 (Medical electrical equipment: Part 1: General requirements for basic safety and essential performance) for Electrical Safety
  - IEC 60601-1-11 (Medical Electrical Equipment: Part 1-11: Requirements for medical electrical systems used in the home healthcare environment) for home healthcare devices
- Software Verification and Validation Testing
  - The results of software verification and validation confirmed that the ZIIP+ Device meets and complies with the applicable software requirements specifications.
- Biocompatibility Evaluation
  - The skin-contacting materials for ZIIP+ are identical to the skin-contacting materials for the predicate ZIIP device, which was evaluated and determined to be biocompatible; therefore, the ZIIP+ Device is biocompatible and substantially equivalent to the predicate device.

In summary, the safety and performance testing results for EMC, Electrical Safety, Wireless Coexistence, and Verification & Validation concluded that the ZIIP+ Device complies with the applicable standards and meets bench testing performance requirements.

9. CONCLUSION

The submitted documentation and performance testing demonstrates that the ZIIP+ device is substantially equivalent to the cited predicate devices in its intended use, principles of operation, design, and overall technological characteristics.