November 21, 2023

NSE Products, Inc
% Jack Slovick
President
Methodize Inc.
24813 Cty 18
Nevis, Minnesota 56467

Re: K232001
Trade/Device Name: Nu Skin RenuSpa iO
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: October 26, 2023
Received: November 1, 2023

Dear Jack Slovick:

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
and Rehabilitation 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)*
K232001

Device Name
Nu Skin RenuSpa iO

Indications for Use *(Describe)*
Nu Skin RenuSpa iO 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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# 510(k) Summary

## K232001

This 510(k) Summary was prepared in accordance with 21 CFR 807.92.

**Date Prepared: 10/26/23**

| | |
|---|---|
| **Submitter/Manufacturer** | Nu Skin Enterprises, Inc<br>75 W. Center St.<br>Provo, UT 84601<br>Establishment Registration # 3001236514 |
| **Submission Correspondent** | Jack Slovick<br>Regulatory Consultant<br>Telephone: 763-639-0238<br>Email: jlslovick@gmail.com |
| **Trade Name** | Nu Skin RenuSpa iO |
| **Regulation Name** | Transcutaneous Electrical Nerve Stimulator for Pain Relief |
| **Regulation Number** | 21 CFR 882.5890 |
| **Product Code** | NFO |
| **Device Class** | Class II |
| **Classification Panel** | Division of Neurological and Physical Medicine Devices |
| **Predicate Devices** | NuBODY Skin Toning Device 510(k)#: **K171588** |
| **Reason for Submission** | New Device |

**Note:** There were no previous submissions for this device.

### Device Description

Nu Skin RenuSpa iO is a hand-held, portable, rechargeable microcurrent device used to stimulate certain parts of the body for aesthetic purposes. It is used with a conductive medium. It contains a rechargeable Lithium-ion battery that is recharged with a USB-enabled inductive charger.

Nu Skin RenuSpa iO is inductively charged by the supplied Nu Skin RenuSpa iO charging stand. Nu Skin RenuSpa iO is designed to mechanically rest on the charging stand in a manner that ensures proper alignment for charging. The charging stand connects to an external AC/DC USB Power supply adapter via a short length of cable terminated with USB-A Male connection.

Nu Skin RenuSpa iO is indicated for use only on healthy, unbroken skin.

Nu Skin RenuSpa iO uses a combination of LED lights and audio feedback.

Nu Skin RenuSpa iO is sold in the United States in a kit with the conductive medium (510k cleared conductive GEL K022006). In all cases the Nu Skin RenuSpa iO and Charger user manual are provided to the user.

**Product Overview**

The Nu Skin RenuSpa iO system (as pictured below) will consist of a topical and hand-held device used together approximately once a day, three days a week on thighs, arms, buttocks and/or abdomen. Suggested treatment duration will be up to five minutes for each area. When treatment has concluded, the device should be gently rinsed with warm water and towel dried.


**Sitting on charger**

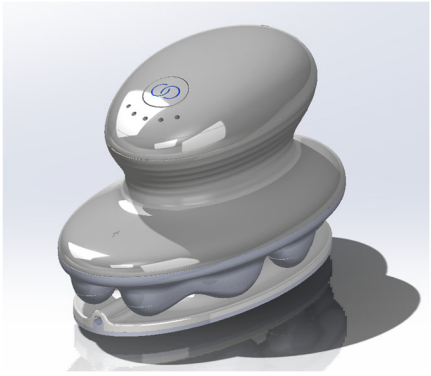

**Figure 1: Nu Skin RenuSpa  iO device and charger**

Nu Skin RenuSpa iO will include an internal (non-removable) lithium-ion battery system that will be charged (inductively) from a low-profile charging base. The user will control

the device via a single button interface. Seven LED indicator positions and an audible alert speaker system will provide user feedback concerning the state of the device (charge, treatment, duration, etc.).


**Figure 2: Cleared Conductive Gel**

This is an already FDA cleared substance supplied with the kit (K022006).

The Nu Skin RenuSpa iO device contains a rechargeable Lithium-ion battery that is recharged with a USB-enabled inductive charger. Key battery characteristics are shown in the following table:

| **Characteristic** | **Specification** |
|---|---|
| Capacity | Typical: 750 mAh |
| Open Circuit Voltage | 3.68~3.92V |
| State of Charge | 50%-80% |
| Weight | 22g |
| Max Voltage | 4.2V |
| Nominal Voltage | 3.6V |
| Fully Discharge Voltage | 3.0V |
| Standard Charge Current | 0.5C |
| Charge time | 3.5 Hours |

**Indications for Use**.
Nu Skin RenuSpa iO is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.

**Comparison of Technological Characteristics with the Predicate Device**
The Nu Skin RenuSpa iO device is substantially equivalent to the predicate device based on comparison of indications for use and technological characteristics. The indications are identical to that of the predicate device NuBODY Skin Toning Device. There are minor differences but mostly similarities between the subject and the predicate device. These differences will be further explained subsequent to the following table.

**Table 1 – General Comparison Table**

| **General Comparison Table** | **Nu Skin RenuSpa iO (New Device)** | **NuBODY (Predicate)** | **Remark** |
|---|---|---|---|
| 510k # | K232001 | K171588 | N/A |
| Indication | Nu Skin RenuSpa iO is intended for body skin stimulation and is indicated for over-the-counter cosmetic use. | NuBODY Skin Toning Device is intended for body skin stimulation and is indicated for over-the-counter cosmetic use. Type of | Same |
| Anatomic Sites | Areas of the body other than the face | Areas of the body other than the face | Same |
| Technological Characteristics | The Nu Skin RenuSpa iO Device is a body skin toning device. Its outer case is injection molded thermoplastic resin. The output contacts consist of chrome-plated elongated spherical electrodes. The RenuSpa iO device is powered by a rechargeable lithium-ion battery. RenuSpa iO device produces microcurrent that is discharged through four | 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, | Difference Note 1 |

| | | | |
|---|---|---|---|
| | fixed, smooth elongated spherical electrodes.<br>To turn the RenuSpa iO device on, the on/off button is pressed.<br>Ascending tonal beeps indicate the RenuSpa iO device is on. Five LED lights illuminate indicating the treatment time duration and the unit is ready for use.<br>The four elongated spheres gently glide over the skin to deliver low-level electrical impulses to targeted locations on the body.<br>The RenuSpa iO device elongated spheres are designed for optimal contact with body skin.<br>The RenuSpa iO 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.<br>The microcurrent output continuously alternates between the positive and negative elongated spherical electrodes.<br>The RenuSpa iO device requires the use of a conductive gel.<br>To promote proper use and provide feedback to the user, the RenuSpa iO device provides | smooth spherical electrodes.<br>To turn the NuBODY device on, the on/off button is pressed.<br>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.<br>The four spheres gently glide over the skin to deliver low-level electrical impulses to targeted locations on the body.<br>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.<br>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.<br>The NuBODY device requires the use of a conductive gel. | |

| | | | |
|---|---|---|---|
| | continuous white noise when the device is in proper contact with the skin. | 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. | |

**Table 2 – Basic Unit Comparison**

| Basic Unit Comparison Table | Nu Skin RenuSpa iO (New Device) | NuBODY (Predicate) | Remark |
|---|---|---|---|
| Power Source | Internal rechargeable Lithium-ion battery | Internal rechargeable Lithium-ion battery | Same |
| a. Method of Line Current Isolation | Type BF | Type BF | Same |
| b. Patient Leakage Current | (See 1) and 2) below) | - | - |
| 1) Normal condition | N/A- Battery Operated | N/A- Battery Operated | Same |
| 2) Single Fault Condition | N/A- Battery Operated | N/A- Battery Operated | Same |
| External power adapter | Nu Skin 5-volt USB-A Wireless Charger. | NuFACE 5-volt power adapter | Difference Note 2 |
| Number of Output Channels | 1 | 1 | Same |
| a) Synchronous or Alternating | N/A - 1 Output channel | N/A - 1 Output channel | Same |
| b) Method of Channel Isolation | N/A - 1 Output channel | N/A - 1 Output channel | Same |
| Regulated Current or Regulated Voltage | Both | Both | Same |
| Software/ Firmware/ Microprocessor Control | Yes | Yes | Same |

| | | | |
|---|---|---|---|
| Automatic Overload Trip | Not required due to circuit design | Not required due to circuit design | Same |
| Automatic Non load Trip | Yes | Yes | Same |
| Automatic Shut Off | Yes | Yes | Same |
| Patient Override Control | Yes | Yes | Same |
| Indicator Display | | | |
| a) On-Off status | Yes | Yes | Same |
| b) Low Battery | Yes | Yes | Same |
| c) Voltage/ Current Level | Yes | Yes | Same |
| Automatic Shut-Off (minutes) | Yes (5minutes) | Yes (5minutes) | Same |
| Compliance with Voluntary Standards | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-10<br>ISO 14971<br>IEC 60601-1-6<br>IEC 62366<br>IEC 60601-1-11 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60529<br>IEC 60601-2-10<br>ISO 14971<br>IEC 60601-1-6<br>IEC 62366 | Difference Note 2 |
| Weight | Approximately 6.7 oz. Without power adapter | Approximately 10-14 oz. without power adapter | Difference Note 3 |
| Dimensions of device(inch) [W x L x D] | Approximately 5.1” x 2.9” x 2.9” | Approximately 2.75" x 6.5" x 6.0" | Difference Note 3 |
| Housing Materials and Construction | Thermoplastic | Thermoplastic | Same |

**Table 3 – Output Specification Comparison Table**

| Output Specification Comparison Table | Nu Skin RenuSpa iO (New Device) | NuBODY (Predicate) | Remark |
|---|---|---|---|
| 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 | Same |
| Shape (e.g., rectangular, spike, rectified sinusoidal) | Voltage Modulated Square | Voltage Modulated Square | Same |
| Maximum Output Voltage | 22 VDC | 28 VDC | Difference Note 4 |
| Maximum Output Current | 640 µA | 900 µA @ 500Ω | Difference Note 4 |
| Maximum Output Current Density | 0.320 mA/cm2 | 0.468 mA/cm2 | Difference Note 4 |
| Output Current when not stimulating | < 1 µA | < 1 µA | Same |
| Output Tolerance | +/- 10% | +/- 10% | Same |
| Pulse Width | 60 ms | 60 ms | Same |
| Frequency (Hz) | Approximately 8.3 Hz | Approximately 8.3 Hz | Same |
| For interferential modes, only | | | |
| a) Beat Frequency (Hz) | No Beat Frequency | No Beat Frequency | Same |
| For multiphasic waveforms, only | | | |
| a) Symmetrical phases | Not Multiphasic | Not Multiphasic | Same |
| b) Phase Duration (include units)<br>c) (state range, if applicable)<br>d) (both phases, if asymmetrical) | Not Multiphasic | Not Multiphasic | Same |
| Net Charge (µC per pulse) | 38.4 µC | 54 µC | Difference Note 4 |

| | | | |
|---|---|---|---|
| Burst Mode (i.e., pulse trains) | | | |
| a) Pulses per burst | 20 | 20 | Same |
| b) Pulses per second | 8.3 | 8.3 | Same |
| c) Burst duration (seconds) | 2.4 s | 2.4 s | Same |
| d) Duty Cycle [Line (b) x line (c)] (on time per burst) | 20.2 s | 20.2 s | Same |
| ON Time (seconds) | 60 msec | 60 msec | Same |
| OFF Time (seconds) | 60 msec | 60 msec | Same |
| Maximum Average Power Density (mW/cm2) | 3.52 | 4.18 | Difference Note 4 |
| Maximum Phase Charge (mC/Burst) | 0.768 | 1.08 | Difference Note 4 |

Nonclinical testing was performed to demonstrate that the Nu Skin product met design specifications and is substantially equivalent to the NUBODY Plus predicate device. This performance testing was conducted using a production equivalent of the Nu Skin, 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 Nu Skin was conducted in accordance with IEC 60601-1 and IEC 60601-1-2. The Nu Skin device conformed to ANSI/AAMI IEC 60601-1: 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 Nu Skin device is substantially equivalent to the NUBODY predicate device.

As such, any differences between the new device and the predicate do not raise any new issues related to safety and efficacy.

## General Comparisons

Technological Characteristics

The new device is similar but slightly different than the predicate in that:

1. The predicate has smooth spherical electrodes as opposed to smooth elongated spherical electrodes in the new device.
2. The predicate LED lights indicate output intensity modification and are not present in the new device. The new device LED lights indicate treatment time elapsed.
3. The predicate allows the user to change intensity and is not present in the new device.
4. The predicate provides feedback of proper use via beep cues every 5 seconds; the new device provides feedback of proper use via continuously emitting white noise.

Therefore, these differences don't raise any new issues related to safety and efficacy.

**Note 1:**

The new device and predicate device have many similarities in technological characteristics except for electrodes, materials, and user interface functions. Both have passed the biocompatibility tests. For more stability and better contact, the proposed device uses fixed, elongated spherical electrodes, and provides user interface functions that differ from the predicate device (audible cues and LED lights). The proposed device has passed the IEC 60601-1, 60601-1-2 tests. Therefore, these differences don't raise any new issues related to safety and efficacy.

## Basic Unit Comparisons

External Power Adapter

The predicate device provides a 5-volt power adapter that plugs in directly into the device via a barrel connection. This power adapter includes a built-in mains wall adapter that is included as part of the power adapter.

The new device provides a 5-volt USB-A power adapter that charges wirelessly. This power adapter does not include a built-in mains wall adapter and relies on a customer provided a certified USB-A mains wall adapter with appropriate electrical ratings. Like the predicate, the new device passes testing as part of AAMI/ANSI IEC 60601-1 for safety and to IEC 60601-1-2 for Electromagnetic Compatibility (EMC). Therefore, these differences don't raise any new issues related to safety and efficacy.

Compliance with Voluntary Standards

The predicate device does not list the IEC 60601-1-11 standard under voluntary compliance. The predicate also explicitly lists IEC 60529.

The new device does list the IEC 60601-1-11 standard due to the use of the device in a home health care environment. The new device does not explicitly list IEC 60529 but rather includes the associated standard as a part of AAMI/ANSI IEC 60601-1 testing. Therefore, these differences don't raise any new issues related to safety and efficacy.

**Note 2:**
The tests performed by our proposed device are slightly different from those of the predicate device. IEC 60529 is the standard for device waterproof level testing, and the waterproof level of our device has been evaluated in the AAMI/ANSI IEC 60601-1 test. The predicate device provided a 5-volt plug in adapter while the new device provides a wireless adapter passed testing as part of AAMI/ANSI IEC 60601-1 for safety and to IEC 60601-1-2 for Electromagnetic Compatibility (EMC). Therefore, these differences don't raise any new issues related to safety and efficacy.

Weight (oz)
The predicate device weighs approximately 10-14 oz. without the power adapter due to older industrial design, internal components, and materials used.
The new device weighs approximately 6.7 oz. without the power adapter due to the newer smaller industrial design, internal components, and materials used to improve device handling. Therefore, these differences don't raise any new issues related to safety and efficacy.

Dimensions (Inches)
The predicate NuFACE device dimensions measure approximately 2.75" x 6.5" x 6.0" due to older industrial design, internal components, and materials used.
The new device dimensions measure approximately 5.1" x 2.9" x 2.9" due to newer smaller industrial design, internal components, and materials used to improve device handling. Therefore, these differences don't raise any new issues related to safety and efficacy.

**Note 3:**
The proposed device is different from the predicate device in housing material, weight, dimensions, and appearance. Both have passed the biocompatibility tests, IEC 60601-1, 60601-1-2 tests. Therefore, these differences don't raise any new issues related to safety and efficacy.

**Output Specification Comparison**
Maximum Output Voltage (V)
The predicate device has a maximum output voltage of 28 VDC.

The new device has a maximum output voltage of 22 VDC. This lowering of the maximum voltage output allows for similar efficacy and is optimal for an improved user experience. Therefore, these differences don't raise any new issues related to safety and efficacy.

Maximum Output Current (uA)

The predicate device has a maximum output current of 900uA at a measured resistance of 500 Ω. The exact maximum output current, regardless of impedance load, is estimated to be around 920 – 940 uA due to calculations around listed specifications and ratings.

The new device has a maximum output current of 640uA and is a true maximum output current with an impedance load approaching 0 Ω. Measurement of the current output at 500 Ω is 620uA. While capable of listing the output current of 620uA at 500 Ω, we believe that 640uA is the true maximum regardless of impedance load. Regardless, this lowering of the maximum voltage current allows for similar efficacy and is optimal for an improved user experience. Therefore, these differences don't raise any new issues related to safety and efficacy.

Maximum Current Density ($mA/cm^2$)

The predicate device has a listed maximum current density of 0.468 $mA/cm^2$.

Using the same methodology, we calculate the new device as having a Maximum Output Current Density of 0.320 $mA/cm^2$. Therefore, these differences don't raise any new issues related to safety and efficacy.

Net Charge per pulse (uC per pulse)

The predicate NuFACE device has a listed Net Charge per pulse of 54uC.

Using the same methodology, our maximum output current, and pulse width, we calculate the new device to have a net charge per pulse of 640uA (*) 60 ms = 38.4 uC per pulse. Therefore, these differences don't raise any new issues related to safety and efficacy.

Maximum Average Power Density ($mW/cm^2$)

The predicate device has a listed maximum current density of 4.18 $mW/cm^2$.

Using the same methodology, our maximum output current density, and maximum output voltage, we calculate the new device as having a Maximum Average Power

Density of 0.320 mA/cm$^2$ (*) 22 VDC (/) 2 = 3.52 mW/cm$^2$. Therefore, these differences don't raise any new issues related to safety and efficacy.

Maximum Phase Charge (mC/Burst)
The predicate device has a Maximum Phase Charge of 1.08 mC/Burst.

Using the same methodology, our Net Charge per pulse, and pulse duration, we calculate the new device to have a Maximum Phase Charge of 0.768 mC/Burst. Therefore, these differences don't raise any new issues related to safety and efficacy.

**Note 4:**
The maximum output voltage and maximum output current of the new device are lower than those of the predicate device to a similar level that allows for similar efficacy and is optimal for an improved user experience.

The net charge, maximum phase charge, maximum current density, and maximum average power density are calculated by different electrode areas and lower maximum ratings. Both meet IEC 60601-2-10 and other IEC 60601 tests. Therefore, these differences don't raise any new issues related to safety and efficacy.

Nonclinical testing was performed to demonstrate that the Nu Skin product met design specifications and is substantially equivalent to the NuBODY Skin Toning Device predicate. This performance testing was conducted using a production equivalent of the Nu Skin, 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 Nu Skin was conducted in accordance with IEC 60601-1 and IEC 60601-1-2. The Nu Skin device conformed to IEC 60601-1-2 Edition 4.0 2014-02 for Electrical and Constructional Safety and to IEC 60601-1-2 Edition 4.0 2014-02 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 Nu Skin device is substantially equivalent to the NUBODY predicate device.

**Performance Data**
To demonstrate the substantial equivalence of the subject Nu Skin RenuSpa iO Device to the selected predicate device, the performance and technological characteristics were evaluated by the completion of the following tests and assessments:

- Design Verification
- SW Verification/Validation
- Electrical Testing
- Packaging Validation
- Bench Testing

**Design Verification**

The following design verification tests were performed on the subject device:

| Test | Test Method Summary | Conclusion |
|---|---|---|
| Dimension verification | Confirms the units meet all dimensional specifications | Acceptance criteria met |
| Visual Inspection | Confirms the product meets all visual specifications | Acceptance criteria met |
| Design Verification | Confirms functionality of units using a clinically relevant bench top model | Acceptance criteria met |
| Software (SW) V&V | Confirms the units meet all SW specifications | Acceptance criteria met |
| Electrical Testing | Confirms electrical functionality of units using a clinically relevant bench top model | Acceptance criteria met |
| Biocompatibility | Confirms the units meet all biocompatibility requirements for this type of device | Acceptance criteria met |
| Cleaning Method Validation | Confirms the units meet all cleaning method expectations for this device | Acceptance criteria met |
| Packaging Distribution Simulation and accelerated aging Testing | Confirms the units meet all packaging distribution simulation and aging requirements | Acceptance criteria met |

Results of tests and assessments did not raise new safety or efficacy questions.

**Clinical Testing**

Not applicable

**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 Nu Skin RenuSpa iO Device is substantially equivalent to the NuBODY device predicate with regards to safety and effectiveness.