K122711



## 510(k) Summary

**Submission Date:** Prepared September 4, 2012, updated September 17, 2013

**Submitter Information:**

*Company Name*: Nu Skin Enterprises, Inc.

*Company Address*: 75 West Center Street
Provo, UT 84601

*Contact Person*: Tyler Whitehead

SEP 17 2013

**Device Information:**

*Trade Name*: Facial Spa

*Common Name*: Facial Toning Device

*Classification Name*: Transcutaneous electrical nerve stimulator 21 CFR 882.5890

*Regulation Class*: Class II

*Product Code*: NFO

**Predicate Devices:** NuFace® Plus (K103472)
Carol Cole Company
Class II

**Device Description:** The Facial Spa is a hand-held, battery-powered device used with conductive treatment gel to stimulate the face with microcurrents.

**Intended Use:** The Facial Spa is intended for the stimulation of healthy facial skin.

**Indications for Use:** The Facial Spa is indicated for facial stimulation for over-the-counter cosmetic use.

**Compliance Data:** The Facial Spa conforms to the applicable requirements of the following standards:

- IEC 60601-1 Issued: 1998/01/01 Ed: 2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; Amendment 1-1991, Amendment 2-1995, Corrigendum – 1995

- IEC 60601-1-2 Issued 2012/06/01 Ed: 3 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-2-10 Issued:1987/01/01 Ed:1 Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Nerve and Muscle Stimulators
- IEC 60601-1-4 Issued: 2000/04/01 Ed:1.1 Medical Electrical Equipment - Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems Consolidated with Amd. 1:1999
- ISO ISO10993-10 / Ed.3, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample Preparation and Reference Material

**Comparison to Predicate Device:**

The Facial Spa is identical to its predicate device in intended use and indications for use. It uses the same technological principle as the predicate device to accomplish its intended use, namely transcutaneous electrical stimulation. Both are hand-held, battery-powered devices. The present device raises no new questions of safety or effectiveness. A technical comparison of the two devices has been completed and supports a substantial equivalence determination.

**Table: Comparison of Nu Skin Facial Spa and Carol Cole NuFace® Plus**

| Features | Nu Skin Facial Spa (Subject Device) | Carol Cole NuFace® Plus (Predicate Device) |
|---|---|---|
| **Similarities** | | |
| Regulation Number | 21 C.F.R. § 882.5890 | 21 C.F.R. § 882.5890 |
| Regulation Name | Transcutaneous Electrical Nerve Stimulator | Transcutaneous Electrical Nerve Stimulator |
| Regulatory Class | Class II | Class II |
| Product Code | NFO | NFO |
| Intended Use | Stimulate the face | Stimulate the face |

| | | |
|---|---|---|
| Indications for Use | Over-the-Counter Cosmetic Use | Over-the-Counter Cosmetic Use |
| Power Source | Battery operated | Battery operated |
| Average DC current through electrodes when device is on but no pulse being applied | 0 | 0 |
| Number of output channels | 1 | 1 |
| Microprocessor controlled | Yes (PLC) | Yes |
| Automatic no-load trip | Yes | Yes |
| Automatic shut off | Yes | Yes |
| User over-ride control | Yes | Yes |
| Indicator Display | | |
| *On/off* | Yes | Yes |
| *Low-battery* | Yes | Yes |
| On Time (seconds) | Constant | Constant |
| Off Time (seconds) | None | None |
| Compliance with Voluntary Standards | IEC 60601-1<br>IEC 60601-1-2 | IEC 60601-1<br>IEC 60601-1-2 |
| Compliance with 21 C.F.R. § 898 | Yes | Yes |
| **Differences** | | |
| Modes | One to Five | One |
| Maximum Output Voltage | @ 500 Ω<br>Mode 1: 188 mV (214 mV)<br>Mode 2: 189 mV (225 mV)<br>Mode 3: 185 mV (220 mV)<br>Mode 4: 184 mV (212 mV)<br>Mode 5: 184 mV (213 mV) | @ 500 Ω<br>137 mV |
| | @ 2k Ω<br>Mode 1: 722 mV (1527 mV)<br>Mode 2: 746 mV (812 mV)<br>Mode 3: 735 mV (815 mV)<br>Mode 4: 740 mV (802 mV)<br>Mode 5: 741 mV (801 mV) | @ 2k Ω<br>769 mV |
| | @ 10 k Ω<br>Mode 1: 2.626 V (2.978 V)<br>Mode 2: 3.787 V (4.011 V)<br>Mode 3: 3.747 V (4.014 V)<br>Mode 4: 3.503 V (3.980 V)<br>Mode 5: 3.729 V (3.980 V) | @ 10 k Ω<br>3.82 V |

| | | |
|---|---|---|
| Maximum Output Current | @ 500 Ω<br>Mode 1: 376 uA (427 uA)<br>Mode 2: 379 uA (449 uA)<br>Mode 3: 371 uA (440 uA)<br>Mode 4: 368 uA (424 uA)<br>Mode 5: 369 uA (427 uA) | @ 500 Ω<br>274 uA |
| | @ 2 k Ω<br>Mode 1: 361 uA (763 uA)<br>Mode 2: 373 uA (406 uA)<br>Mode 3: 367 uA (407 uA)<br>Mode 4: 370 uA (401 uA)<br>Mode 5: 370 uA (400 uA) | @ 2 k Ω<br>387 uA |
| | @ 10 k Ω<br>Mode 1: 362 uA (398 uA)<br>Mode 2: 379 uA (401 uA)<br>Mode 3: 375 uA (401 uA)<br>Mode 4: 350 uA (398 uA)<br>Mode 5: 373 uA (398 uA) | @ 10 k Ω<br>383 uA |
| Waveform | Direct Current | Pulsed Monophasic |
| Weight | 120 g (approx. 4 oz) | 9 oz |
| Dimensions | *Facial Spa with Large Conductor:* 143 x 31.2 x 67.5 mm (5.6" x 1.2" x 2.7")<br><br>*Facial Spa with Small Conductor:* 136 x 31.2 x 67.5 mm (5.4" x 1.2" x 2.7") | 3" x 5.25" x 1.25" |
| Housing material and construction | ABS, Chrome plated<br>ABS, rubber (elastomer) | Thermo Plastic |

**Conclusion:** The Facial Spa is substantially equivalent to the predicate device, as the devices share a common intended use, and technological differences between the Facial Spa and the predicate do not raise new questions of safety or effectiveness.

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

September 17, 2013

NuSkin Enterprises, Inc.
C/O Paul D. Rubin
Ropes & Gray LLP
One Metro Center
700 12th Street, Suite 900
Washington, DC 20005

Re: K122711
Trade/Device Name: NuSkin Facial Spa
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator
Regulatory Class: Class II
Product Code: NFO
Dated: September 4, 2013
Received: September 4, 2013

Dear Mr. Rubin,

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K122711

Device Name: NuSkin Facial Spa

Indications For Use:

The Facial Spa is indicated for facial stimulation for over-the-counter cosmetic use.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S