DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 23, 2016

Trophy Skin, Inc.
% Sue Anthoney-Dewet
FDA Consultant
Aegis Regulatory, Inc.
2424 Dempster Drive
Coralville, IA 52241

Re: K152199
Trade/Device Name: RejuvatoneMD
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO
Dated: February 17, 2016
Received: February 23, 2016

Dear Ms. Anthoney-Dewet:

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 and Part 809); 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 and Part 809), 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 -A

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)*
K152199

Device Name
RejuvatoneMD

Indications for Use *(Describe)*
The RejuvatoneMD 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.

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510(k) Summary

K152199

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR § 807.92

Date Prepared: March 23, 2016

1. Submitter Information: AEGIS Regulatory, Inc. – Susan Anthoney-DeWet

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On Behalf of Sponsor: Trophy Skin, Inc.

Attn: Imran Karim, President

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2. General Information

2.1 Classification Name: Transcutaneous Electrical Nerve Stimulator for Aesthetic Purposes

2.2 Common/Usual Name: TENS Device

2.3 Proprietary Names: RejuvatoneMD

2.4 Classification: Class II

2.5 Classification Number: 882.5890

2.6 Review Panel: Neurology

2.6 Product Code: NFO

3. Device Description:

The **RejuvatoneMD** device is a non-invasive at-home facial stimulation device intended for cosmetic use. The device works by delivering low-level electrical microcurrent impulses through dual contact spheres to strategic locations on the face and allows users to adjust the output level for personalized comfort.

4. Indications / Intended Use:

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

Rx or OTC:

The labeling, instructions, and User Operations (21 CFR § 801.60 and 61), are designed for layman understanding and use. The predicate devices are indicated for (OTC) use.

5. Predicate Device:

The RejuvatoneMD device is substantially equivalent in design, function and intended use to the following predicate device:
1. K133823 – NuFace Mini (Carol Cole Company)

6. Technological Characteristics and Substantial Equivalence

The technological characteristics of the RejuvatoneMD device and the predicate device, are substantially equivalent in that both devices are designed to provide electrical stimulation to the facial skin for cosmetic use. The RejuvatoneMD and the predicate device function using the same mode of action by producing microcurrent that is discharged through electrodes that are in contact with the patient's skin, and both have user adjustable settings . The technical characteristics and physical properties presented in this submission demonstrate that the RejuvatoneMD device is substantially equivalent in design, function and intended use to the predicate device.

Sections below compare the characteristics of the RejuvatoneMD and the predicate device:

Elements of Comparison		Subject Device	Predicate Device
Device Name and Model		RejuvatoneMD, Model: TSTONEMD	NuFACE® Mini Device
510(k) Number		Applying	K133823
Product Code		NFO	NFO
Manufacturer		Trophy Skin, Inc.	Carol Cole Company
Intended Use		This device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.	The NuFACE® Mini Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.
Power Source(s)		9V battery (Type: 6LR61)	2 rechargeable AA NiMH batteries
Applied Part		Type BF	Type BF
Patient Leakage Current	NC	60µA Comply with IEC 60601-1 and IEC 60601-2-10	56µA Comply with IEC 60601-1 and IEC 60601-2-10
	SFC	360µA Comply with IEC 60601-1 and IEC 60601-2-10	374µA Comply with IEC 60601-1 and IEC 60601-2-10
Average DC current through electrodes when device is on but no pulses are being applied		0A	--
Number of Output Channels		One channel	One channel
Number of Output Modes		1 mode	1 mode
Output Intensity Level		5 steps	3 steps
Synchronous or Alternating?		N/A - 1 Output Channel	N/A - 1 Output Channel
Method of Channel Isolation		N/A - 1 Output Channel	N/A - 1 Output Channel
Regulated Current or Regulated Voltage?		Both	Both

Elements of Comparison		Subject Device	Predicate Device
Software/Firmware/Microprocessor Control?		Yes	Yes
Automatic Overload Trip		Not required due to circuit design	Not required due to circuit design
Automatic No-Load Trip		No	Yes
Automatic Shut Off		Yes	Yes
Patient Override Control		Yes	Yes
Indicator Display	On/Off Status	Yes	Yes
	Low Battery	No	Yes
	Voltage/ Current Level	Yes	Yes
Timer Range		Yes (20 minutes)	Yes (21 minutes)
LCD Display		No	No
Compliance with Voluntary Standards		Yes Comply with IEC 60601-1 and IEC 60601-2-10, IEC 60601-1-2	Yes Comply with IEC 60601-1 and IEC 60601-1-2
Biocompatibility		All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.
Compliance* with 21 CFR 898		Yes	Yes
Main Unit Weight		248g	816g
Dimensions		55.0mm x 35.0mm x 177.2mm (L x W x H)	2.5” W x 4.2” L x 1.2” D
Electrode Size		0.81cm²	--
Housing Materials and Construction		Housing made from ABS plastic and output contacts made from ACD12 Chrome.	Thermo Plastic
Environment for operating		Temperature: 5 ~ 45°	Temperature: 5 ~ 40° C

Elements of Comparison	Subject Device	Predicate Device
	Humidity: 20 ~ 65% RH	Humidity: 20 ~ 65% RH
Environment for storage	Temperature: 0 ~ 45° Humidity: 10 ~ 90% RH	Temperature: 0 ~ 40° C Humidity: 10 ~ 90% RH
Waveform	Pulsed Monophasic	Pulsed Monophasic
Shape	Modulated Square	Modulated Square
Maximum Output Voltage(+/- 10%)	256mV@500Ω	222mV@ 500Ω
	806mV@2KΩ	781mV@ 2KΩ
	4.02V@10KΩ	3.90V@ 10KΩ
Maximum Output Current(+/- 10%)	512μA @ 500Ω	396μA @ 500Ω
	403μA @ 2KΩ	395μA @ 2KΩ
	403μA @ 10KΩ	391μA @10KΩ
Pulse Duration	ON phase: 60 ms OFF phase: 60 ms Total Pulse Width: 120 ms	ON phase: 60.4 ms OFF phase: 60.4 ms Total Pulse Width: 120.8 ms
Pulse Frequency	8.33Hz	8.28 Hz
Net Charge (per pulse)	0μC @ 500Ω	1.43μC @ 500Ω
Maximum Phase Charge	24.18μC @ 500Ω	23.7μC @ 500Ω
Maximum Current Density	0.498mA/cm^2@500Ω (Minimum Electrode Contact Area:0.81cm^2)	0.514mA/cm^2@500Ω (Minimum Electrode Contact Area:0.771cm^2)
Maximum Average Power Density	32.77μW/cm^2 @500Ω (Minimum Electrode Contact Area:0.81cm^2)	99.05μW/cm^2 @500Ω (Minimum Electrode Contact Area:0.771cm^2)
Maximum Power Density	2005μW/ cm2@10kΩ(Minimum Electrode Contact Area: 0.81cm^2)	1981μW/ cm2@10kΩ(Minimum Electrode Contact Area: 0.771cm^2)

Elements of Comparison		Subject Device	Predicate Device
Burst Mode (i.e., pulse trains)	a. Pulses per burst	20	20
	b. Pulses per second	8.33	8.28
	c. Burst duration (seconds)	2.4	2.42
	d. Duty Cycle[line (b)×line (c)]	20	20
Contraction and Relaxation Time		Adjustable, due to different modes.	Adjustable, due to different modes.

The RejuvatoneMD has similar technological characteristics with the predicate device in the product design, material, program mode and output waveform.

There are minor differences between the RejuvatoneMD device and the predicate device in the electrode size and subsequently the output characteristics including “Maximum Output Voltage”, “Maximum Output Current”, “Pulse Duration”, “Pulse Frequency”, “Net Charge (per pulse)”, “Maximum Average Current”, “Maximum Phase Charge”, “Maximum Current Density”, “Maximum Average Power Density”, and “Burst Mode (i.e., pulse trains).” The output specification of the RejuvatoneMD device is very close to the predicate device in these areas and within an acceptable range. Both the predicate device and the RejuvatoneMD device comply with IEC 60601-1, IEC 60601-2-10 requirement. So the differences of function specification do not raise any safety or effectiveness issue and does not effect the determination of substantial equivalence.

7. Performance Testing and Standards:

Safety & performance testing demonstrates that the RejuvatoneMD is at least as safe and effective as the legally marketed predicate device.

The RejuvatoneMD device has been tested and conforms to international consensus standards:

ELECTRICAL SAFETY:
Recognition Number 19-4:

- **IEC/EN 60601-1:2005 Edition 3/(R)2012 And A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC))**

PERFORMANCE:
Recognition Number 17-11:

- **IEC 60601-2-10 Edition 2.0 2012-06, Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators. (Neurology)**

EMC:

Recognition Number 19-1:

- **IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests. (General II (ES/EMC))**

LABEL VALIDATION:

A Usability/Label Comprehension Study was conducted in order to validate the device labeling with 30 participants.

The results of the final study group found that over 95% of the participants were able to:

- Correctly Self-Select the device as the correct or incorrect device for themselves
- Correctly complete the Comprehension portion of the study
- Correctly perform the Device Use portion of the study

In addition to the testing above, the RejuvatoneMD was designed referencing the following standards and FDA Guidance documents:

USABILITY:

Recognition Number 5-85:

- IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for safety – Collateral Standard: Usability Edition 3.0, 2010

Recognition Number 5-67:

- **IEC 62366:2007/(R)2013, Medical Devices - Application Of Usability Engineering To Medical Devices. (General I (QS/RM))**

RISK MANAGEMENT:

Recognition Number 5-40:

- ISO 14971:2007, ed.2 + MDD 93/42/EEC Annex I, IEC 60601-1, ed. 3+A1**, Medical Devices - Application Of Risk Management To Medical Devices. (General I (QS/RM))**

SOFTWARE DESIGN:

Recognition Number 13-8:

- **IEC 62304 First Edition 2006-05, Medical Device Software - Software Life Cycle Processes. (Software/Informatics)**
- ***Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005; and***
- ***General Principles of Software Validation: Final Guidance for Industry and FDA Staff, January 11, 2002***

8. Substantial Equivalence Conclusion

After an analysis of the safety, indications, intended uses, performance features, design materials, biocompatibility, power output, technological properties, treatment areas, treatment regimes and

methods of operation, the Sponsor believes that no significant differences exist between the device and the predicate device. Minor differences in the technological characteristics of the RejuvatoneMD device and the predicate devices do not raise any issues of safety or effectiveness Therefore substantial equivalency is requested.