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

November 25, 2015

Pretika Corporation
Thomas Nichols
President
12215 Holly Street
Riverside, California 92509

Re: K150077
Trade/Device Name: SonicLift, Model ST261
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO, IRO
Dated: January 4, 2015
Received: February 19, 2015

Dear Thomas Nichols:

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,

Carlos L. Pena -S

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)*
K150077

Device Name
SonicLift, Model: ST261

Indications for Use *(Describe)*
This 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.

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Chapter 6. 510(k) Summary

Date of the summary prepared: November 24, 2015

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- 510(k) Owner's Name: Pretika Corporation
- Establishment registration number: Applying
- Address: 12215 Holly Street, Riverside, CA 92509 USA
- Phone: 949-481-8818
- Fax: 949-481-8828
- Contact Person (including title): Thomas Nichols (president)
- E-mail: thomasnichols@pretika.com

2. Subject Device Information

- Trade Name: SonicLift, Model: ST261
- Common Name: Facial Toning Device
- Classification name: Transcutaneous Electrical Nerve Stimulator for Aesthetic Purposes
- Review Panel: Neurology, Physical Medicine
- Product Code: NFO, IRO
- Regulation Class: 2
- Regulation Number: 882.5890, 890.5975

3. Predicate Device Information

Sponsor	Carol Cole Company	WAHL CLIPPER CORP
Device Name	NuFace	WAHL FRESH FACE
510(k) Number	K072260	K944909
Product Code	NFO	IRO
Regulation Number	882.5890	890.5975

Regulation Class	2	1

4. Device Description

SonicLift (Model: ST261) is a non-invasive facial toning device intended for at-home cosmetic use. It has two treatment modes – Vibration Mode and Micro-current Mode. In the Vibration Mode, mechanical vibration at the frequency of 108.7Hz can help to relax facial muscles. In the Micro-current Mode, the low voltage micro-current impulses are emitted from dual probes that are designed for optimal contact with faces of all shapes and sizes. SonicLift, Model: ST261 allows you to adjust the current output from 0 to 280 microamps for a personalized comfort level.

The SonicLift (Model: ST261) is not for use on injured or otherwise impaired skin or muscles, and in any therapy for the treatment, or prevention of any disease. This device is not for use near any devices with Electromagnetic Interference (EMI), such as cell phones, MRI, CT, RFID etc. or MR environment. This device must only be used for the purpose stated – namely for the stimulation of facial muscles as indicated in the instruction manual for personal beauty purposes. All other uses shall be deemed improper.

The conductive gel used along with the SonicLift, Model: ST261 is the K983964 Batch #6060 Conductive Gel (Skylark Device CO. LTD).

5. Intended Use / Indications for Use

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

6. Materials

There are four user directly contracting components in the subject device as the following list.

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Housing	ABS plastic	Surface-contacting device: skin	Maximum 2 hours (< 24hours)
Output contacts	Stainless steel	Surface-contacting device: skin	Maximum 2 hours (< 24hours)
Side edge and button	Mixing silicone	Surface-contacting device: skin	Maximum 2 hours (< 24hours)
Conductive gel	Aqua (water), propylene glycol, carbomer, Triethanolamine, phenoxyethanol.	Surface-contacting device: skin	Maximum 2 hours (< 24hours)

The subject device SonicLift, Model: ST261 contacts with the body is surface, skin contact with transient contact duration (less than 24 hours). According to Table 1 - Initial evaluation tests for consideration in ISO 10993-1, the applicable biological effect is:

Cytotoxicity
Sensitization
Irritation or intracutaneous reactivity

Therefore, the following biological evaluation tests were conducted to demonstrate the safety of the direct user contacting elements in the subject SonicLift. The tests were conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58). Please refer to Attachment 5 for detail.

1. Cytotoxicity Test
(1) Test Method
MTT Method in ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, Edition 3.0, 2009;
(2)Passing Criteria
As our subject device is only for limited skin contacting, we set the criteria for NON-TOXIC to be “no more than Grade 2” according to United States Pharmacopoeia.
(3) Test Result
The Cytotoxicity test result showed the device had no toxicity to L929 cell. The test result is passed the criteria.

2. Skin Sensitization Test
(1) Test Method
Guinea Pig Maximization Test in ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization, Edition 3.0, 2010;
(2)Passing Criteria
As our subject device is for limited skin contacting, we set the criteria to be “Grade 0” according to United States Pharmacopoeia.
(3) Test Result
The Skin Sensitization test result for device is Grade 0. The test result is passed the criteria.

3. Skin Irritation Test
(1) Test Method
0.9% Sodium Chlorid Injection and Sesame oil Extract in ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization, Edition 3.0, 2010;

(2)Passing Criteria

As our subject device is for limited skin contacting, we set the criteria to be “0-0.4 for Irritation Index” according to United States Pharmacopoeia.

(3) Test Result

The Skin Irritation test results for Component is 0 for Irritation Index. The test result is passed the criteria.

7. Physical characteristics

Basic Unit Characteristics	
Power Source	3.7V li-battery
Method of Line Current Isolation	Type BF Applied Part
Patient leakage current	Comply with IEC 60601-1 and IEC 60601-2-10
- Normal Condition	--
- Single Fault Condition	--
Average DC current through electrodes when device is on but no pulses are being applied	0A
Number of channels	1
Number of modes	2
Output Intensity Level	4
Regulated Current or Regulated Voltage?	Current Control
Software/Firmware/Microprocessor Control?	Yes
Automatic Overload Trip?	No
Automatic No-Load Trip?	No
Automatic Shut Off?	No
User Override Control?	Yes
Indicator	Indicates on/off status, low battery, LED of mode information, intensity level information.
Time Range (minutes)	No
Compliance with Voluntary Standards	Yes Comply with IEC 60601-1 and IEC 60601-2-10, IEC 60601-1-2
Compliance* with 21 CFR 898	Yes
Main Unit Weight	248g
Accessories Weight	Charge station: 200g; Charger Adapter: 180g
Main Unit Dimension	3.7" L x 7.6" W x 2.8" D
Charger lead wire length	1.6m
Housing Materials of main unit	Housing made from ABS plastic and output contacts made from stainless steel.
Accessories Materials	Plastic

Vibration Mode Specification	
Frequency	108.7 Hz
Micro-Current Mode Specification	
Waveform and Shape	Pulsed, symmetric biphasic, rectangular
Maximum Output Voltage (+/- 10%)	156mV @ 500Ω 0.78V @ 2kΩ 2.6V @ 10kΩ
Maximum Output Current (+/- 10%)	0.31mA @ 500Ω 0.39mA @ 2kΩ 0.26mA @ 10kΩ
Net Charge (per pulse)	0 mC @500Ω
Phase Charge	21μC @ 500Ω
Maximum Current Density	0.0194mA/cm^2@500Ω (The Electrode Size: 16cm^2)
Maximum Power Density	3μW/cm^2@500Ω(The Electrode Size:16cm^2)
Pulse Width	56 ms
Pulse Duration	112 ms
Frequency	8.93 Hz
Contraction and Relaxation Time	Due to different modes. (See below “Program Specification Table”)
Additional Features	
Environment for operation	Temperature: 5 ~ 40°C Humidity: ≤ 80% RH
Environment for storage	Temperature: 0 ~ 45°C Humidity: ≤ 93% RH

8. Test Summary

SonicLift, Model: ST261 has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Software verification and validation test according to the requirements of the FDA “Guidance for Pre Market Submissions and for Software Contained in Medical Devices”
- The waveform test report has also been conducted to verify the output parameters of the device.

9. Comparison to predicate device and conclusion

The SonicLift (Model: ST261) shares the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate devices, the Nuface (Model: NU-4003) and the WAHL FRESH FACE.

As the SonicLift has a main function of facial stimulation and an auxiliary function of vibration, the classification product code is NFO while the subsequent product code is IRO (510(k)-exempt). Thereof, the facial simulator Nuface (Model: NU-4003) is regarded as the main predicate device. Besides, we select the facial vibrator WAHL FRESH FACE as an auxiliary predicate device.

In addition, a review of the predicate devices demonstrates that the SonicLift (Model: ST261) is safe and effective as the predicate devices as they share equivalent technological characteristics, features, specifications and materials, and are used to perform the same indicated use. Therefore the proposed device is substantially equivalent (SE) to the predicate devices.
The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness

Elements of Comparison		**Subject Device**	**Predicate Device**		**Remark**
Device Name and Model		SonicLift, Model: ST261	Nuface, Model: NU-4003	WAHL FRESH FACE	--
510(k) Number		Applying	K072260	K944909	--
Manufacturer		Pretika Corporation	Carol Cole Company	WAHL CLIPPER CORP.	--
Intended Use		This device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.	The NuFace Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.	The Wahl Fresh Face is intended for facial stimulation and is indicated for over-the-counter cosmetic use.	SE
Basic Unit Characteristics					
Power Source(s)		3.7V li-battery	9V AAA batteries	--	SE Note 1
Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage Current	NC	Comply with IEC 60601-1 and IEC 60601-2-10	--	--	SE Note 1
	SFC				
Average DC current through electrodes when device is on but no pulses are being applied		0A	--	--	SE Note 1
Number of Output Channels		One channel	One channel	One channel	SE
Number of Output Modes		2 modes	1 mode	--	SE Note 1

Elements of Comparison		**Subject Device**	**Predicate Device**		**Remark**
Output Intensity Level		4 steps	2 steps	--	SE Note 1
Synchronous or Alternating?		N/A	Alternating	--	SE
Method of Channel Isolation		N/A	Voltage Isolation	--	SE
Regulated Current or Regulated Voltage?		Current Control	Current Control	--	SE
Software/Firmware/Microprocessor Control?		Yes	Yes	--	SE
Automatic Overload Trip		No	No	--	SE
Automatic No-Load Trip		No	No	--	SE
Automatic Shut Off		No	No	--	SE
Patient Override Control		Yes	Yes	--	SE
Indicator Display	On/Off Status	Yes	Yes	--	SE
	Low Battery	Yes	No	--	SE Note 1
	Voltage/ Current Level	Yes	No	--	SE Note 1
Timer Range		No	No	--	SE
LCD Display		No	Indicate the following information: on/off status, low battery	--	SE Note 1
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 60601-2-10, IEC 60601-1-2	Yes Comply with IEC 60601-1 and IEC 60601-2-10, IEC 60601-1-2	SE
Compliance* with		Yes	Yes	Yes	SE

Elements of Comparison	**Subject Device**	**Predicate Device**		**Remark**
21 CFR 898				
Weight	Main unit: 248g Charge station: 200g Charger Adapter: 180g	816g	--	SE Note 2
Dimensions	3.7" L x 7.6" W x 2.8" D	177.8 x 63.5 x 25.4 mm (7'' L x 2.5'' W x 1'' D)	--	SE Note 2
Electrode Size	16 cm^2	--	--	SE Note 2
Housing Materials and Construction	ABS plastic	ABS plastic	--	SE
Output Specifications				
Waveform	Pulsed Biphasic	Pulsed Monophasic	--	SE Note 3
Shape	Rectangular	Rectangular	--	SE
Maximum Output Voltage(+/- 10%)	156mV @ 500Ω	0.158V@ 500Ω	--	SE Note 3
	0.78V @ 2kΩ	0.78V@ 2KΩ	--	
	2.6V@10KΩ	2.6V@ 10KΩ	--	
Maximum Output Current(+/- 10%)	0.31mA @ 500Ω	0.223mA@ 500Ω	--	SE Note 3
	0.39mA @ 2kΩ	0.358mA@ 2KΩ	--	
	0.26mA @ 10kΩ	0.263mA@10KΩ	--	
Pulse Duration	112 ms	112 ms	--	SE
Pulse Frequency	8.93Hz	8.93Hz	--	SE
Net Charge (per pulse)	0mC @ 500Ω	0.0062μC @ 500Ω	--	SE Note 3
Maximum Average Current	0.198mA @500Ω	--	--	SE Note 3
Maximum Current Density (r.m.s)	0.0194mA/cm^2@500Ω (The Electrode Size: 16cm^2)	0.341 mA/cm^2@500Ω	--	SE Note 3
Maximum Average Power Density	3μW/cm^2@500Ω(The Electrode Size:16cm^2)	3.02μW/cm^2@500Ω	--	SE Note 3
Contraction and Relaxation Time	Adjustable, due to different modes. (See below "Program Specification Table")	Adjustable, due to different modes.	--	SE

Elements of Comparison	Subject Device	Predicate Device		Remark
Additional Features				
Environment for operating	Temperature: 5 ~ 40°C Humidity: ≤ 80% RH	Temperature: 5 ~ 40° C Humidity: 20 ~ 65% RH	--	SE Note 1
Environment for storage	Temperature: 0 ~ 45°C Humidity: ≤ 93% RH	Temperature: 0 ~40°C Humidity: 10 ~90%RH	--	SE Note 1
Standards				
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.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

Some of the basic unit characteristics, such as “Power Source(s)”, “ Weight”, “ Dimensions”, “Operating Environment”, “Storage Environment”, “Number of Output Modes”, ”Output Intensity Level” and “Indicator Display of Voltage/ Current Level” are a little different from the predicate devices. However, it will not affect the main function and the intended use of the device as they all also comply with IEC 60601-1 requirements. Bisides, the subtle changes of the physical characteristics will not affect the critical functions or the normal use.So the differences will not raise any safety or effectiveness issue.

Note 2:

Although some of the simulation characteristics, such as “ Maximum Output Voltage(+/- 10%)”, “Maximum Output Current(+/- 10%)”, “Pulse Duration”, “Pulse Frequency” and “Net Charge (per pulse)” of subject device are different from the simulator predicate device Nuface, they are all proved by waveform report and performance report. And they comply with IEC 60601-1, IEC 60601-2-10 requirements, FDA guidance requirement for Transcutaneous Electrical Nerve Stimulator for Pain Relief and FDA guidance requirement for Powered Muscle Stimulator for Muscle Conditioning. So the differences of the physics specifications will not raise any safety or effectiveness issue.

Note 3:

Although the “Maximum Output Voltage”, “Maximum Output Current”, “Net Charge (per pulse)”, “Maximum Average Current”, “Maximum Current Density”, “Maximum Average Power Density” of subject device are a little different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-10 requirement, FDA guidance requirement for Transcutaneous Electrical Nerve Stimulator for Pain Relief and FDA guidance requirement for Powered Muscle Stimulator for Muscle Conditioning. So the differences of function specification will not raise any safety or effectiveness issue.

Finial Conclusion:

The subject device “SonicLift, Model: ST261” is Substantial Equivalence to all predicate devices.