K130065

APR 30 2014

Section 005 – Traditional 510(k) Summary

As required in 21 CFR807.92, we hereby submit this Traditional 510(k) Summary.

Traditional 510(k) owners name, address, phone, fax, contact person & preparation date

The Traditional 510(k) owner is Biosonic Technologies, LLC.

Address: 333 Las Olas Way, Suite 1906

Fort Lauderdale, FL 33311

Phone: (954) 300 - 2511

Fax: (866) 830 - 8759

The contact person is Mr. Ray Baker, President, Biosonic Technologies, LLC.

Traditional 510(k) preparation date: 19 August, 2011

SUBJECT DEVICE:

Name of the device, trade name, proprietary name, and classification name:

Trade name: Beautiful Image Model 900 Facial Toning Device

Common name: Facial Toning Device

Classification: Stimulator, Transcutaneous Electrical, Aesthetic Purposes.

CFR Reference: 21 CFR 882.5890

Product Code: NFO

Device Description:

Beautiful Image Model 900 Facial Toning Device is intended for facial stimulation and is indicated for prescription cosmetic use. The anatomical site for application of the Model 900 is the face.

To enhance safety, the device is operated only from battery voltage and will not operate while connected to line power. A proper recharge should be performed prior to using the machine.

The Model 900 is microprocessor controlled and housed in a white plastic case.

SPECIFICATIONS:

Dimensions & Appearance:	
Height (rear)	5.5 inches (13.97 cm)
Height (front)	3.3 inches (8.38 cm)
Width	15.3 inches (38.86 cm)
Depth	11.3 inches (28.7 cm)
Weight	10.0 pounds (4.5 kgs)
Color	White case with blue front panel
Electrical Specifications	
Device power	Model 900 will operate only on battery power; it will not operate on line voltage
Device Output	800µA maximum, from constant current source
Complex wave output frequency	3 Hz to 300 Hz
Maximum voltage	30Vpp on any output with respect to common; 5Vpp typical
Battery Charger	9vdc @ 1 amp. Use of the charger disables the patient circuits
Battery	6 volt, 7 amp hours
Power Requirements CAC Adapter	
Input Voltage	100 to 120 VAC, 60 Hz
Input Current	0.15 amps
Configuration	Standard U.S. 2-Prong Plug
Device output Voltage	9v DC
Output Current	1 amp
Output Plug	De coas: 5.5mm OD, 2.1mm pin receptacle
Cable length	6 ft (240 cm)
Environmental Specifications	
Operating Temperature	+ 50 to 104° F (+10 to +40°C)
Storage Temperature	- 29 to + 167° F (-34 to +76° C)
Humidity	0 to 95% - non-condensing

FUNCTIONAL DESCRIPTION

OPERATING CYCLE:

The Model 900 operating cycle is initiated by momentarily pressing the POWER button located in the POWER section of the front panel. All indicator lights (LEDs) on the panel will illuminate for a short period of time except for the CHARGING and the BATTERY LOW or BATTERY FULL indicators (depending on the charge level of the battery).

The INTERVAL PACE lights (located in the WAVEFORM section of the panel) will step from left to right providing a visual indication of the approximate delay time remaining prior to the application of energy to the probes. The INTERVAL DELAY adjustment sets the amount of time for this delay.

The SEQUENCING lights (also located in the WAVEFORM section of the panel) indicate the application of each of the different waveform outputs from the equipment, seven in total. The SEQUENCE DURATION adjustment sets the amount of time for the total sequenced set.

OPERATING RANGES:

Adjustment of the output energy intensity is set by the INTENSITY ADJUSTMENT button located in the PROCEDURE section of the panel. Each press of the button will advance the output energy from NORMAL, to MODERATE, to HIGH, and then the sequence will repeat.

The INTERVAL DELAY provides an adjustment range of approximately 1 to 6 seconds.

The SEQUENCE DURATION provides an adjustment range of approximately 10 to 30 seconds.

Waveform frequencies: automatically sequencing from 3 Hz to 300 Hz

OPERATING MODE:

An indicator shows that the wand set is in use. The indicator will be illuminated when the wand is connected to the machine.

CALIBRATION:

The Model 900 does not require calibration.

INDICATION FOR USE:

The Beautiful Image Model 900 Facial Toning Device uses microcurrent electrical energy to stimulate facial tissues for aesthetic purposes.

INTENDED USE:

Biosonic Technologies Model 900 Facial Toning Device is intended for facial stimulation and is indicated for prescription cosmetic use. The anatomical site for application of the Model 900 is the face.

COMPARISON WITH THE PREDICATE DEVICE:

The predicate device for this Traditional 510(k) is the NūFace Facial Toning Device. The subject device is Biosonic Technologies Beautiful Image Model 900 Facial Toning Device, that is substantially equivalent to the predicate device, differing only in that the unit is larger and designed to support the handheld operation of the contacts from a desktop device by means of cables, and is intended for the use of licensed practitioners rather than the public.

COMPARISON OF THE SUBJECT DEVICE AND PREDICATE DEVICE PARAMETERS:

Parameter	Your Device	Predicate Device
510(k) Number	K130065	K072260
Device Name and Model	Model 900	NuFace Original
Manufacturer	Biosonic Technologies, LLC	Carol Cole Company
Power Source(s)†	One 6V battery	One 9V battery
- Method of Line Current Isolation	N/A	N/A
- Patient Leakage Current††	N/A	N/A
- Normal Condition (μA)	N/A	N/A
- Single Fault Condition (μA)	N/A	N/A
Average DC current through electrodes when device is on but no pulses are being applied (μA)	None	None
Number of Output Modes †††	One	One
Number of Output Channels††††	One	One
Synchronous or Alternating?	N/A	N/A

Parameter		Your Device	Predicate Device
Method of Channel Isolation		N/A	N/A
Regulated Current or Regulated Voltage?		Both	Both
Software/Firmware/Microprocessor Control?		Yes	No
Automatic Overload Trip?		Yes	No
Automatic No-Load Trip?		Yes	No
Automatic Shut Off?		Yes	No
User Override Control?		Yes	Yes
Indicator Display Status			
	On/Off Display Status?	Yes	Yes
	Low Battery?	Yes	No
	Voltage/Current Level?	Yes	No
Timer Range (minutes)		None	None
Compliance with Voluntary Standards?		IEC 60601-1	IEC 60601-1
Compliance with 21 CFR 898?		Yes	Yes
Weight (lbs., oz.)		10lbs	0.5lbs
Dimensions (in.) [W x H x D]		5.5x15.3x11.3	2.25x7x0.75
Housing Materials and Construction		Thermoplastic	Thermoplastic

† For AC line-powered devices, we recommend that you specify the line voltage and frequency, the method of line current isolation, and the measured patient leakage current. For battery-powered devices, we recommend that you specify the number, size and type of batteries.

†† We recommend that you follow IEC 60601-1 "Medical Electrical Equipment – Part 1: General Requirements for Safety" or an equivalent method to show that the levels of patient leakage current, measured under both normal and single fault conditions, are acceptable.

††† For devices with more than one output mode, we recommend that you provide the information in Output Waveforms (see Section 7A above) and Output Specifications (see Section 7C below) for each output mode.

†††† For devices with more than one output channel, we recommend that you describe whether the outputs are delivered in a synchronous and/or alternating fashion and the method of achieving channel isolation.

Parameter	Your Device	Predicate Device

Parameter		Your Device	Predicate Device
Mode or Program Name		Beautiful Image	NuFace
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Pulsed Monophasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular
Maximum Output Voltage (volts) (+/- 5%)		0.347 @500Ω	0.16 @500Ω
		1.242 @ 2 kΩ	0.78 @ 2 kΩ
		5.780 @10 kΩ	2.6 @10 kΩ
Maximum Output Current (mA) (+/- 5%)		0.647 @500Ω	0.324 @500Ω
		0.625 @ 2 kΩ	0.358 @ 2 kΩ
		0.584 @10 kΩ	0.263 @10 kΩ
Duration of primary (depolarizing) phase† (msec) *See Note 3*		0.648 - 322	----
Pulse Duration† (msec)		3.24 – 1610	----
~~Frequency~~† (Hz) [or Rate† (pps)]		0.621 – 308.6	----
For multiphasic waveforms only:	Symmetrical phases?	Yes	Yes / No
	Phase Duration† (msec), (state range, if applicable), (both phases, if asymmetrical	0.324-161	pulsed
Net Charge (micro coulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		0μC @500Ω	N/A @500Ω
Maximum Phase Charge, (μC)		190 @500Ω	18.13 @500Ω
Maximum Current Density, †† (mA/cm², r.m.s.)		1.486 @500Ω	0.341 @500Ω
Maximum Average Current (average absolute value), mA		0.493 @500Ω	---- @500Ω
Maximum Average Power Density, †† (W/cm²), (using smallest electrode conductive surface area)		366E-6 @500Ω	3.02μW@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	2.1
	(b) Bursts per second	N/A	9.1
	(c) Burst duration (seconds)	N/A	2.3
	(d) Duty Cycle: Line (b) x Line (c)	N/A	20.9
ON Time (seconds)		10-30	Constant
OFF Time (seconds)		1-6	None
Additional Features (specify, if applicable)		None	None

† For continuously variable parameters, we recommend that you specify the full range; for parameters with discrete settings, we recommend that you specify all available selections.

†† We recommend that you calculate the maximum current density and maximum average power density values by using the conductive surface area of the smallest electrodes intended for use with the unit, and include sample calculations in your 510(k). We also recommend that you calculate the maximum power density by using the maximum duty cycle and by averaging over output duration of one second. The maximum average power density should be less than 0.25 watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns.

DISCUSSION OF WHY THE DIFFERENCES BETWEEN THE SUBJECT DEVICE AND THE PREDICATE DEVICE DO NOT ADVERSELY AFFECT SAFETY AND EFFECTIVENESS:

The predicate device has a 9v battery, while the subject device has a 6v battery. Generally, a lower voltage battery represents a lower risk factor, and this advantage counts in favor of the Model 900 while providing the device ample power to perform in its intended use. Furthermore, the predicate device does not have any software/firmware/microprocessor control, automatic overload trip, automatic no-load trip, automatic shutoff, low battery indicator display status, nor voltage/current level indicator display status. Each of these safety features exists within the subject device, and therefore provides a safer device than the predicate device. Additionally, the predicate device is much smaller and lighter than the robust Model 900, which will not as easily move about and is designed in this fashion in direct response to user design inputs. Regarding the current, the maximum current density of the Model 900 measures 1.486 mA/cm2 r.m.s. at 500 Ohms of resistance, versus the reported 0.341 mA/cm2 r.m.s. at 500 Ohms resistance of the NūFace, and although this appears to represent a difference within the overall current, it reflects simply a more precise surface contact area that applies the microcurrent as compared to the predicate. The overall current delivered from the Model 900 is unchanged. Finally, the maximum average power density is 366E-6 W at 500 Ohms versus 3.02 µW at 500 Ohms, which represents a larger energy output than the predicate, given the more precise surface contact area, while remaining as safe as the predicate, and more effective at the point of contact than the predicate. Thus, given the foregoing, the Model 900 is at least as safe and as effective as the predicate NūFace device.

All other parameters including the intended use and safety profile remain unchanged.

NONCLINICAL TEST DATA:

Product Safety testing and electromagnetic compatibility testing conforming to IEC 60601-1 and IEC 60601-1-2, and biocompatibility testing conforming to ISO 10993 were performed in support of the overall safety and effectiveness characteristics of the device, and have confirmed that the Model 900 is safe, effective and substantially equivalent regarding the outputs of the predicate device.

SUMMARY:

No new issues of safety or effectiveness are raised regarding the Model 900 Facial Toning Device.

End of Traditional 510(k) Summary Section

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

April 30, 2014

Biosonic Technologies, LLC
c/o Shepard G. Bentley
Bentley Biomedical Consulting, LLC
28241 Crown Valley Parkway, Suite 510(K)
Laguna Niguel, CA 92677

Re: K130065
Trade/Device Name: Beautiful Image Model 900 Facial Toning Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO
Dated: March 30, 2014
Received: April 1, 2014

Dear Mr. Bentley:

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" (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 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,

Felipe Aguel -S

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 on last page.

510(k) Number *(if known)*
K130065

Device Name
Beautiful Image Model 900 Facial Toning Device

Indications for Use *(Describe)*
The Beautiful Image Model 900 Facial Toning Device uses microcurrent electrical energy to stimulate facial tissues for aesthetic purposes.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.04.30 16:54:05 -04'00'

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