DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 18, 2016

Aime Medical, Inc
% Mr. John O'Brien
Regulatory Consultant
AJW Technology Consultants, Inc.
445 Apollo Beach Blvd.
Apollo Beach, Florida 33572

Re: K151722
Trade/Device Name: Slim UP ULTRA
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: February 18, 2016
Received: February 19, 2016

Dear Mr. O'Brien:

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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K151722

Device Name
SLIM UP® ULTRA

Indications for Use *(Describe)*
Slim UP® ULTRA is indicated for the use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrode for the purpose of improvement of muscle tone of buttocks muscles.

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
(As required by 807.92)

I. SUBMITTER

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II. DEVICE

Name of Device:	Slim UP® ULTRA
Common or Usual Name:	Power muscle Stimulator.
Classification Name:	Power Muscle Stimulator
Regulation Number:	890.5850
Device Panel:	Physical Medicine
Regulatory Class:	II
Main Product Code:	NGX

III. PREDICATE DEVICE

510(k) Number:	K123075
Product Code:	NGX
Manufacturer:	Well Life Healthcare Limited
Trade Name:	Buttock Muscle Stimulator Model WL 2413B; Buttock Muscle Stimulator Model WL-2413E

The predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Slim UP® ULTRA is a new beauty appliance that works on the principles of Electrostimulation.

Slim UP® is used in environments such as Health Spa's and Beauty Salons.

Slim UP® ULTRA has following major components:

- Main power switch
- Control panel
- Infrared unit
- Distribution of electro-stimulation channels.

Slim UP® ULTRA electrostimulation section has 8 channels 8 channels for body electrostimulation with compensated two-phase rectangular waveform, with individual intensity adjustment and 5 different multi-phase treatment programs diversified to meet the needs of the single case.

Slim UP® ULTRA infrared section has 6 infrared ray sources housed in a height-adjustable, mobile arm that adapts to any couch, ensuring the ideal working distance is maintained at all times. IR source is used for patient comfort only. It does not have any therapeutic effect.

Slim UP® ULTRA is a latest-generation machine occupying only half a square meter. It can be located in any booth, can be adapted to any bed and can be moved anywhere.

The table below describes the list of associated accessories included with device.

Description	Quantity
Polycarbonate arc	1
100W IR lamp	7
Nylon screw+ washer for fixing the polycarbonate arc	5
Protective goggles	3
4 mm hexagonal wrench	1
Threaded pivot for fixing IR apparatus	2
Temperature probe	1
Disc for electrostimulation	100
510k cleared electrode with conductive gel under (K091163)	54

V. INDICATIONS FOR USE

Slim UP® ULTRA is indicated for the use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrode for the purpose of improvement of muscle tone of buttocks muscles.

I. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Subject and predicate devices are intended for similar treatment condition based on the principle of operation they uses.

Parameter	Slim UP® ULTRA	Predicate Device	Predicate Difference
Name of Device	**Slim UP® ULTRA**	**Buttock Muscle Stimulator (WL 2413 E Model)**	-
Product Code	NGX, NUV	NGX	-
Regulation Number	878.4810, 890.5850	890.5850	-
510 K Number	K151722	K123075	-
Intended use	Slim UP® ULTRA is indicated for the use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrode for the purpose of improvement of muscle tone of buttocks muscles.	Buttock Muscle Stimulator, model WL-2413E, is -intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrode for the purpose of improvement of muscle tone of the buttocks muscles	Same

Parameter	Slim UP® ULTRA	Predicate Device	Predicate Difference
Name of Device	**Slim UP® ULTRA**	**Buttock Muscle Stimulator (WL 2413 E Model)**	**-**
Product Component	1. Main power switch 2. Control panel 3. Infrared generation unit 4. Electro-stimulation channels 5. Skin contact electrodes	1. Electronic Stimulator Module 2. Skin contact electrodes 3. Conductive gel, 4. 3AAA batteries, 5. 2 read wires 6. Storage bag	Same
Treatment Energy	Electrostimulation	Electrostimulation	Same
Energy source	1) 16 Electrodes (K091163) 2) 6 IR Lamps	K082065, Silicon pad electrodes (7.0 cm diameter)	Different
Pigmentation Effect	No	No	Similar
Dimensions	95 cm x 129 cm x 187 cm (W*D*H)	64 X20 X90 (W*D*H)	Different
Weight	161 Kg	0.08 Kg (80 Gm) (including batteries)	Different
Electrical Requirement	230VAC, Single-phase	1.5 V x 3 AAA size battery	Different
Safety features and compliance with safety standard	Compliant	Compliant	Same
Patient body contact material	Biocompatible	Biocompatible	Same

Parameter	Slim UP® ULTRA	Predicate Device	Predicate Difference
Name of Device	**Slim UP® ULTRA**	**Buttock Muscle Stimulator (WL 2413 E Model)**	-
Treatment Time	Between 15 and 60 minutes depend on treatment program selected	20-40 Minutes	Different
Compliance with Voluntary Standards?	Compliant	Compliant	Same
Housing Materials and Construction	Polycarbonate arc Nylon screw and washer for fixing the polycarbonate arc	ABS	Different
Principle of Operation	Slim UP® ULTRA works on the basic principles of Electrostimulation. Skin contact electrodes are applied on treatment area.	The Buttock Muscle Stimulator, model WL-241 3E, comprises an electronic stimulator module with silicon pad electrodes which connect the signals from the stimulator to the skin. The electrodes are placed on skin	Same
Anatomical Site of Application	Buttocks	Buttocks	Same
Number of Electrode Used	16 Electrostimulation electrode	K082065, Silicon Pad Electrode (7.0 cm diameter)	Different
Mode OR Program name	2 TONE (F2 work phase)	WL-2413E	Different
Wave form	Biphasic	Biphasic	Same
Shape	Rectangular	Rectangular	Same

Parameter		Slim UP® ULTRA	Predicate Device	Predicate Difference
Name of Device		**Slim UP® ULTRA**	**Buttock Muscle Stimulator (WL 2413 E Model)**	-
Maximum output voltage		100Vpp @ 500Ω 184Vpp @ 1 KΩ 234Vpp @ 2 KΩ 240Vpp @ 10 KΩ (Single Phase)	40.8 V @500Ω 70.0 V @2kΩ 106.0 V @10kΩ	Different
Maximum output current		100mA @ 500Ω 92 mA @ 1 KΩ 58.5 mA @ 2 KΩ 12 mA @ 10 KΩ (calculated on single positive pulse)	8l.6mA@500 Ω 35.0mAr@2kΩ 10.6mA@10kΩ	Different
Duration of primary phase (µsec)		400 µsec	300 µsec	Different
Pulse duration		400 µsec	720 µsec	Different
Frequency (Hz)		40 Hz	70 Hz	Different
For multiphase waveforms only	Symmetrical phases	Yes	Yes	Same
	Phase duration	800 µsec	Not Applicable	
Method of Line current Isolation		Type BF	Type BF	Same
Number of output mode			04	
Pulse per burst		Same for each program	Same for each program	Same
Burst per second		Same for each program	Same for each program	Same

Parameter	Slim UP® ULTRA	Predicate Device	Predicate Difference
Name of Device	**Slim UP® ULTRA**	**Buttock Muscle Stimulator (WL 2413 E Model)**	-
Burst duration	Same for each program	Same for each program	Same
Duty cycle	Same for each program	Same for each program	Same
Method of achieving zero net charge /pulse	Biphasic symmetric wave for each pulse	Biphasic symmetric wave for each pulse	Same
Regulated Current or Regulated Voltage?	Voltage	Voltage	Same
Software/Firmware/Microprocessor control?	Yes	Yes	Same
Automatic Shut Off?	Yes	Yes	Same
RMS (Root Mean Square) Current	100mA during the active phase of the current pulse, square wave with null medium value and period of 600µs	38.644mA (500Ω) 16.907 mA (2KΩ) 5.120 mA (10 Ω)	Different
Prescription or OTC	Prescription	OTC	Different
Number of Treatment Programs	7 different programs that should be chosen based on the individual requirements of each case	N/A	Different
Method for Channel Isolation	Sole transformer on all channels from 12V and the tension that goes to the electrostimulation channels (it is not an insulating transformer). If current goes over 100mA (short output transistor) a safety circuit intervenes by resetting the machine	Output coil	Different
Sterilization	Provided Non Sterile	Provided Non sterile	Same

Significant output characteristics:

Comparison Feature	Slim UP Ultra	Predicate Device	Remarks
Net Charge	0 @ 500Ω (symmetrical positive and negative pulses)	0 (symmetrical stimulation biphasic wave)	Same
Max Phase Charge	40 µC @ 500Ω	24µc	Differnt
Max Average Current Density (jmax)	0.089 mA/cm² @ 500Ω	0.0997 mA/cm2	Different
Max Power Density (W/cm^2)	0.00014 W/cm^2 @ 500Ω with electrodes 4x9 cm	0.00399 watts/cm2	Different
Burst Mode	Yes	Yes	Same

Similarities in Technological characteristics:

- Intended use
- Product components
- Treatment energy
- Pigmentation effect
- Safety feature and compliance with safety standard
- Patient body contact material
- Compliance with voluntary standards
- Principle of operation
- Anatomical site of application
- Waveform
- Shape
- Symmetrical phases for multiphase waveform only
- Method of line current isolation
- Number of output mode
- Pulse per Burst
- Burst per Second
- Bust duration
- Duty cycle
- Method for achieving zero net charge/pulse
- Current/ Voltage regulation
- Software/firmware control
- Automatic shut off
- Sterilization
- Net Charge
- Max Phase Charge
- Burst Mode

Differences in Technological characteristics

- Energy Source
- Physical characteristics (weight, dimensions)
- Electrical Requirements
- Treatment Time
- Housing material & construction
- Number of Electrode
- Mode or program name
- Maximum output voltage
- Maximum output current
- Duration of primary phase

- Pulse duration
- Frequency
- Root Mean Square (RMS) Current
- Prescription or OTC
- Number of Treatment programs
- Method for channel isolation
- Maximum Phase Charge
- Max. current density
- Max. power density

Justification of predicate differences:

Differernce-1: Energy Source - IR source
Predicate device: Buttock muscle stimulator does not contain IR modality.
New Device: The Slim UP® ULTRA contains IR modality in addition to Electrostimulation modality.
Intended Use: Same
Different questions of Safety and effectiveness? No
Justification of Difference:
IR source does not have any therapeutic effect it is just used for patient comfort only. Also IR modality used in subject device is not able to raise and maintain body temperature above 38-41 degree Celsius for 10 minutes. IR source used in Slim UP® ULTRA is similar to reference device i.e. Syneron Medical's Velashape (K122579). So this minor technological difference does not raise any new questions of safety and efficacy.

Difference-2: Physical Characteristics (Dimension and weight)

Predicate device: Buttock muscle stimulator is 0.08 Kg in weight and has physical dimensions of 64cm Width X20cm Diameter X90 cm Height.
New Device: The Slim UP® ULTRA has physical dimension of 95cm Width X 129cm Diameter X 187cm Height and 161 Kg in weight.
Intended Use: Same
Different questions of Safety and effectiveness? No
Justification of Difference:
The difference in physical dimensions and weight doesn't introduce any additional safety issues. Due to its compact size Slim UP® ULTRA can be located in any booth, can be adapted to any bed and can be moved anywhere.

Difference-3: Housing material and construction

Predicate device:
Buttock muscle stimulator has asbestos as primary housing material.
New Device:
Different parts of Slim UP® ULTRA were made from different housing material. It has polycarbonate arc, nylon screw and washer for fixing the polycarbonate arc.
Intended Use: Same
Different questions of Safety and effectiveness? No
Justification of difference:
This predicate difference will not raise any questions of safety and efficacy as patient body contact parts of Slim UP® ULTRA are biocompatible and Slim UP® ULTRA complies with international safety standard EN ISO 14121-1:2007- Safety of the equipment, Risk evaluation part-1: Principles.

Difference-4: Number of electrodes

Predicate device: The information regarding number of electrodes in predicate device is not available.
New device: Slim UP® ULTRA has 16 skin contact electrodes.
Intended Use: Same
Different questions of Safety and effectiveness? No
Justification of difference:
The difference in number of electrodes do not raise new question of safety or effectiveness. Slim UP® ULTRA use 510k cleared electrode FIAB PG474W (K091163). Apart from this electromagnetic safety of subject device has been established by conducting EMC testing in complies with international EMC standard 60601-1, 60601-1-2 and 60601-2-10. So this difference will not raise any additional questions of safety and efficacy.

Difference-5: Functional parameters like Mode or Program name, Pulse duration, Number of output mode, pulse per burst, burst per second, Burst duration, Duty cycle, RMS current, Number of treatment program Method of channel isolation, Maximum current and power density.

Predicate device:
Buttock muscle stimulator has following different functional parameters:
Mode or Program name: WL-2413E
Pulse Duration: 720 µsec
Number of output mode: 04
Pulse per burst: Same for each program
Burst per second: Same for each program

Burst duration: Same for each program
Duty cycle: Same for each program
RMS current: 38.644mA (500Ω), 16.907mA (2KΩ), 5.120 mA (10 Ω)
Number of treatment program: N/A
Method of Channel isolation: Output coil
Maximum Current density: 0.0997 mA/cm^2
Maximum Power density: 0.00399 watts/cm^2

New Device:
Slim UP® ULTRA has following different functional parameters:
Mode or Program name: 2 TONE (F2 work phase)
Pulse Duration: 400 µsec
Number of output mode: N/A
Pulse per burst: 160
Burst per second: 1/8
Burst duration: 4 Sec
Duty cycle: 1/2
RMS current: 100mA during the active phase of the current pulse, square wave with null medium value and period of 600µs
Number of treatment program: 7 different programs that should be chosen based on the individual requirements of each case.
Method of channel isolation: Sole transformer on all channels from 12V and the tension that goes to the electrostimulation channels (it is not an insulating transformer). If current goes over 100mA (short output transistor) a safety circuit intervenes by resetting the machine
Maximum current density: 2, 8 mA/cm² @ 500Ω
Maximum power density: 8, 96 mW/cm² @ 500Ω with electrodes 4x9 cm
Intended Use: Same
Different questions of safety and effectiveness: No
Justification of difference:
The minor difference in functional parameter between predicate device and subject device do not raise new questions of safety or efficacy as Electromagnetic safety of Slim UP® ULTRA has been established by conducting EMC testing in complies with international EMC standard 60601-1, 60601-1-2 and 60601-2-10.

Difference-6: Electrical Requirement

Predicate device:
Runs on 3 AAA batteries at 1.5v.
New Device:
230VAC, Single-Phase
Intended Use: Same
Different questions of Safety and effectiveness? No
Justification of difference:

The difference in Electrical Requirements between predicate device and subject device do not raise new questions of safety or efficacy as Electromagnetic safety of Slim UP® ULTRA has been established by conducting EMC testing in complies with international EMC standard 60601-1, 60601-1-2 and 60601-2-10.

The conclusion of this technical comparison is that Slim UP® ULTRA is substantially equivalent to the Buttock Muscle Stimulator and have been verified by subsequent testing. Any difference between Predicate device and Slim UP® ULTRA do not raise any new questions for safety and efficacy.

PERFORMANCE DATA

The following performance testing was provided in support of the substantial equivalence determination.

Biocompatibility Testing

Patient applied parts of Slim UP® ULTRA are biocompatible as per the International standard ISO 10993-1:2009- Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Electrical safety and electromagnetic compatibility (EMC)

The following standards have been complied within designing, manufacturing and testing of Slim UP® ULTRA:

- IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Safety.
- IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-2-10:2000: Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- EN ISO 14121-1:2007- Safety of machinery -- Risk assessment -- Part 1: Principles.

Software Verification and Validation Testing

Software validation was completed to check the safety requirements implemented by the firmware resident on the Microcontroller used on the Slim Up® Ultra, in order to provide objective evidence that the firmware itself operates as indicated in the user manual and does not cause any risks connected to its use.

I. CONCLUSION

The performance data demonstrates that the Slim UP® ULTRA performs as intended and similar to that of predicate devices and exhibits comparable mechanical, functional and technological characteristics to that of the predicate device.

Any technological or engineering differences existing between subject device and predicate devices is insignificant in terms with safety and effectiveness of subject device.

Based on these factors, the Slim UP® ULTRA can be considered substantially equivalent to the predicate device and safe and effective for its intended use.