



Food and Drug Administration
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December 1, 2016

AK Beauty Enterprises, LLC
% Thomas C. Knott
Senior Regulatory Advisor
Benjamin L. England and Associates, LLC
810 Landmark Dr, Suite 126
Glen Burnie, Maryland 21061

Re: K152420
Trade/Device Name: AK Body Toning Device
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 29, 2016
Received: November 1, 2016

Dear Thomas C. Knott:

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,

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

Indications for Use

510(k) Number (if known)

K152420

Device Name

AK Body Toning Device

Indications for Use (Describe)

The AK Body Toning Device is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin-contact electrodes in order to improve or facilitate muscle performance.

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 (21 CFR 807.92)

I. SUBMITTER

AK Beauty Enterprises, LLC
436 North Bedford Dr. Suite 203
Beverly Hills, CA 90210

Phone: (310) 550-7747
Fax: (310) 550-8822

Contact Person: Robert Applebaum, MD
Date Prepared: August 20, 2015

II. DEVICE

Name of Device: AK Body Toning Device
Common or Usual Name: Muscle Stimulation Device
Classification Name: Powered Muscle Stimulator for Muscle Conditioning
Regulatory Class: 21 CFR 890.5850, Class II
Product Code: NGX

III. PREDICATE DEVICE

- K083140; Compex Sport Plus manufactured by DJO, LLC

These predicates have not been subject to a design-related recall.¹

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The AK Body Toning Device is a battery-operated, hand-held, single-program, muscle stimulation system to tone healthy muscles of the abdomen, thighs, and buttock. The device is self-contained with three rows of axels under a rounded unit with a handle that is shaped to allow a comfortable hand-grip for the user. Each axel has three knobbed wheels. The two sets of stainless steel wheels on the ends are the powered electrodes and the middle set of plastic wheels allows for easier movement across the skin.

The device produces transcutaneous electrical muscle stimulation through the powered electrodes that are approximately four inches apart. An on-off switch applies the power and an adjustable knob sets the intensity of the treatment. An electroconductive gel is applied to the skin in the area to be treated and the device is rolled across the treatment area. The knob is adjusted until the treatment is effective and may be increased after initial use.

V. INDICATIONS FOR USE

The AK Body Toning Device is intended to for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin-contact electrodes in order to improve or facilitate muscle performance.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

¹ On July 9, 2012, section 605 of FDASIA (Pub. L. 112-144) added section 518A to the FD&C Act, which directs FDA to establish a program to routinely and systematically assess information regarding device recalls, and to use that information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. FDA believes that one way to carry out this directive is to provide greater transparency on recalled devices. Identifying whether a predicate was recalled is optional, but doing so would help the Agency achieve this FDASIA directive.

The AK Body Toning Device is substantially equivalent to other legally marketed muscle stimulation devices cleared under product code NGX. The intended use of the AK Body Toning Device is the same as the predicate devices. All are intended for use on healthy muscles to improve muscle tone and are not intended to treat any diseases and are contraindicated for use on unhealthy muscles.

The AK Body Toning Device uses the same electrical stimulation principals as the predicate device. The AK Body Toning Device delivers the stimulation through rolling electrodes versus fixed electrodes in the predicate devices. However, the basic unit characteristics and output specifications of the AK Body Toning Device are substantially equivalent to the predicate devices. The rolling electrodes do not raise any new questions of safety or effectiveness. On the other hand, because the electrodes are moved across the treatment area and do not stay in one place, the AK Body Toning Device provides an extra measure of safety from consequences like skin burns, while effectively delivering electrical stimulation to a broader area during a treatment session. Thus, the AK Body Toning Device is substantially equivalent to existing predicate devices with the NGX product code.

Parameter		AK Beauty Enterprises, LLC	Compex Sport Plus
<u>BASIC UNIT CHARACTERISTICS</u>			
510(k) Number		K152420	K083140
Device Name and Model		AK Body Toning Device	Compex Sport Plus
Manufacturer		AK Beauty Enterprises, LLC	DJO LLC
FDA Product Code		NGX	NGX
Power Source(s) [†]		Battery 3 x 1.5 V AAA batteries	Rechargeable Ni-Mh Battery 4.6V (4 cells AA=R6)
- Method of Line Current Isolation		N/A - Internal Power Type BF	N/A (battery operated device)
- Patient Leakage Current ^{††}		N/A (battery operated device)	N/A (battery operated device)
- Normal Condition (µA)		N/A (battery operated device)	N/A (battery operated device)
- Single Fault Condition (µA)		N/A (battery operated device)	N/A (battery operated device)
Number of Output Modes ^{†††}		1	One (NMES)
Number of Output Channels: ^{††††}	Synchronous or Alternating?	N/A Single channel.	4 Synchronous, but never 2 channels activated at the same time
	Method of Channel Isolation	N/A Single Channel	Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state
Regulated Current or Regulated Voltage?		Voltage	Regulated current (all channels)

Parameter		AK Beauty Enterprises, LLC	Compex Sport Plus
Software/Firmware/Microprocessor Control?		No	Yes
Automatic Overload Trip?		No	Yes
Automatic No-Load Trip?		No	Yes
Automatic Shut Off?		Yes	“On/Off” switch
User Override Control?		Yes	Yes
Indicator Display:	On/Off Status?	Yes	Yes
	Low Battery?	No	Yes
	Voltage/Current Level?	Proportional Voltage level indicator	Yes, unit = [Energy]
Timer Range (minutes)		5 min	Maximum = 55 minute Screen shows remaining time in minutes and seconds and displays countdown timer
Compliance with Voluntary Standards?		-IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) -IEC 60601-1-2:2007 (Third Edition) -UL 60601-1 (2003) CSA C22.2 No. 601.1 (2003) -IEC 60601-2-10: 2012 (Second Edition)	IEC 60601-1 IEC 60601-2-10
Compliance with 21 CFR 898?		N/A (electrodes are integral with the device, there are no separate leads)	
Weight (lbs., oz.)		800 g	300 [g]
Dimensions (in.) [W x H x D]		3.12 x 3.51x 7.0 (IN)	99 x 142 x 36 [mm] 3.9 x 5.6 x 1.4 [in]
Housing Materials and Construction		ABS	
<u>OUTPUT SPECIFICATIONS</u>			
Mode or Program Name			
Waveform (e.g., pulsed monophasic, biphasic)		Monophasic	Symmetrical Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular
Maximum Output Voltage (volts) (+/- 10%)		10.4 V @500Ω	60 V @500Ω
		35.6 V @ 2 kΩ	165 V @ 2 kΩ
		88.0 v @10 kΩ	165 V @ 10 kΩ
Maximum Output Current (specify units) (+/- 10%)		22 mA @500Ω	120 mA
		18 mA @ 2 kΩ	82 mA @ 2 kΩ

Parameter		AK Beauty Enterprises, LLC	Compex Sport Plus
		9 mA @10 kΩ	16 mA @ 10 kΩ
Duration of primary (depolarizing) phase [†] (μsec)			
Max Pulse Duration [†] (μsec)		1000 μsec	800 μsec
Frequency [†] (Hz) [or Rate [†] (pps)]		75 Hz	1 – 120 Hz
For interferential modes only: Beat Frequency [†] (Hz)		N/A	
For multiphasic waveforms only:	Symmetrical phases?	N/A (not multiphasic)	Symmetrical, 400 μsec ea phase
	Phase Duration [†] (include units),		
	(state range, if applicable),		
	(both phases, if asymmetrical)		
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		22.5 μC @500Ω	0 μC @ 500Ω Excitation pulse fully compensated
Maximum Phase Charge, (μC)		22.5 μC @500Ω	48 [μC] @ 500Ω
Maximum Current Density, ^{††} (mA/cm ² , r.m.s.)		4.17 mA/cm ² @500Ω ?	1.49 mA/cm ² @ 500Ω
Maximum Average Power Density, ^{††} (W/cm ²), (using smallest electrode conductive surface area)		0.0089W/cm ² @ 500Ω	27.6 mW/cm ² @500Ω 0.0276 W/cm ² @ 500Ω
Burst Mode ^{†††} (i.e., pulse trains):	(a) Pulses per burst	N/A, no burst mode	
	(b) Bursts per second		
	(c) Burst duration (seconds)		
	(d) Duty Cycle: Line (b) x Line (c)		
ON Time (seconds)			
OFF Time (seconds)			
Additional Features (specify, if applicable)		Electrodes are integrated within the unit;	

Parameter	AK Beauty Enterprises, LLC	Compex Sport Plus
Intended Use	The AK Body Toning Device is intended to for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin-contact electrodes in order to improve or facilitate muscle performance.	The Compex® Sport Plus is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Performance testing

A study observed muscle movement by ultrasound imaging. Real-time stimulation of the anterior thigh muscle was recorded using the AK device (while being held stationary and while being rolled) and the predicate device. The muscle stimulation was similar for the AK Body Toning Device and the predicate device.

Biocompatibility testing

The biocompatibility evaluation for the skin contact materials used in the AK Body Toning Device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Electrical safety and electromagnetic compatibility (EMC)

Performance and electrical safety testing were conducted on the AK Body Toning Device. The test results demonstrate that the device safely performs as intended and raised no new questions of safety or performance compared to the predicate devices. Internationally recognized standards include:

- IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012)
- IEC 60601-1-2:2007 (Third Edition)
- UL 60601-1 (2003)
- CSA C22.2 No. 601.1 (2003)
- IEC 60601-2-10: 2012 (Second Edition)

VIII. CONCLUSIONS

The AK Body Toning Device is substantially equivalent the predicate device. They both are intended to stimulate healthy muscles to improve or facilitate muscle performance. They stimulate the muscles by delivering electrical current through electrodes to the skin to cause muscle contraction. The predicate is indicated for several muscle groups but the AK Body Toning Device is limited to the abdomen, buttocks and thighs. Their technological characteristics differ in that the AK Body Toning Device uses rolling electrodes but the predicate device uses fixed electrodes. The data indicates that the AK Body toning Device works as safely and effectively as the predicate device.

--- END OF 510(K) SUMMARY ---