February 26, 2019

A-1 Engineering
% Peter Knauer
Principal Consultant
Sage BioPartners
1741 Little Kate Rd
Park City, Utah 84060

Re: K182440
Trade/Device Name: Body System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: November 26, 2018
Received: November 27, 2018

Dear Peter Knauer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182440

Device Name
Body System

Indications for Use *(Describe)*
The Body System is intended for muscle conditioning to stimulate healthy muscles.

The Body System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The Body System is intended to be operated by a trained professional who is present to monitor treatment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510(k) Summary / Statement - 21 CFR 807.92(a)

This 510(k) Summary for the Body System is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) Summary.

Applicant Name:	A-1 Engineering
Applicant Address:	30 Mauchly, Suite A Irvine, CA 92618
Official Contact:	Tony Picciano, Owner
Telephone:	(949) 748-7488
Email:	tony6213@yahoo.com
Submission Date:	November 26, 2018
Subject Device:	Trade Name: Body System Common Name: Muscle stimulator for conditioning.
Regulation Description:	Powdered Muscle Stimulator
Classification:	Regulatory Class II, 21 CFR 890.5850
Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Product Code:	NGX
Device Description	Body System (available in models: SX101 and OS2911). Both models utilize the same internal electrical components. The models differ only in the control/display features and exterior casing/dimensions.The Body

System is a Powered Muscle Stimulator with 16 channel ports using self adhesive pad applicators attached to the body for muscle conditioning. The pad applicator is a 510K cleared device (K970426), itself.

The Body System uses the same technological characteristics as the predicate devices (listed below); it is an electrically powered device that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area. The Body System muscle stimulators provide selections of different programs through manual adjustment of five different frequency programs of the device from 200 Hz, to 1250 Hz. The Body System has a maximum output voltage of 88V @ 2k Ω, rated at 200 volts. A display shows the balance treatment time. The output signal is biphasic, rectangular and based on a voltage and current regulated technology. All channel outputs are isolated from each other; they have their own transformers and amplifiers which are Independent from neighboring channels or outputs. The only commonality between the outputs are their connectors to the power supply, the start button, the programs button, and the pulse button. The Body System power source is 110 V - 240 V AC Mains, 50-60 Hz. The patient leakage current tested at 240VAC 60Hz is 5 microamps for both the normal and fault conditions. The Body System Channels are synchronous and are isolated by separate transformers.

The Intended Use of the Body System has the same key elements as the predicates: for muscle conditioning to stimulate healthy muscle. There are no differences in Intended Use amongst the predicates.

Indications for use: The Body System is intended for muscle conditioning to stimulate healthy muscles.

The Body System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The Body Sy is intended to be operated by a trained professional who is present to monit treatment.

Predicate Device: The Body System is substantially equivalent to the predicate devices listed below:

- K123158, Ion Magnum Genius, under 21 CFR 890.5850 and Product Code NGX

Predicate Trade Name: Ion Magnum Genius

Classification Name: Stimulator, Muscle, Powered for Muscle Conditioning
Premarket Notification: K123158
Manufacturer: Ion Genius, Inc.

- K143551, Compex Wireless USA, under 21 CFR 890.5850 and Product Code NGX

Predicate Trade Name: Compex Wireless USA

Classification Name: Stimulator, Muscle, Powered for Muscle Conditioning
Premarket Notification: K143551
Manufacturer: DJO, LLC

Based on the intended use/Indications for use, design, materials, principle of operation, energy used and materials, the Body System is substantially equivalent to the legally marketed predicate devices. The non-clinical performance data demonstrates substantial equivalence and includes an analysis of output waveforms.

Non-Clinical Tests Performed on the Device:

The Body System has been tested to establish is safety and performance. The following tests have been performed on the patient contacting parts:

- Biocompatibility – Cytotoxicity (ISO-10993-5) – result: Pass
- Biocompatibility – irritation (ISO-10993-10) – result: Pass
- Biocompatibility – Sensitization (ISO-10993-10) – result: Pass
- Performance – including Output Waveforms of the Body System as compared to a predicate
- Electromagnetic Compatibility – according to EN 60601-1-2:2015, IEC 60601-1-2:2014, IEC 60601-2-10 2012 + A1 2016
- Electrical Safety – according to IEC 60601-1-6:2010, AMD1:2013, IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)

Summary:

There are no differences in the technological characteristics between the subject device and the predicate devices, which raise issues concerning safety, performance or efficacy. The Body System is substantially equivalent to the predicate device(s) in terms of safety and effectiveness.

Comparison of the Subject and Predicate Devices				
Elements of Comparison	**Subject device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Similar/Different**
Device Name and Model	Body System	Ion Magnum Genius	Compex Wireless USA	N/A
510 (K) Number	Subject of this submission	K123158	K143551	N/A
Product Code	NGX	NGX	NGX	Similar
Regulation Number	890.5850	890.5850	890.5850	Similar
Indications for Use	The Body System is intended for muscle conditioning to stimulate healthy muscles. The Body System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The Body System is intended to be operated by a trained professional who is present to monitor treatment.	Ion Magnum Genius is intended for muscle conditioning to stimulate healthy muscles. The Ion Magnum Genius is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Ion Magnum Genius programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The Ion Magnum Genius is only	The Compex Wireless USA is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. The Compex Wireless USA is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the Compex Wireless USA stimulation programs are designed for injured or disease afflicted muscles. Its use on such muscles is	Similar – although there are some differences in the exact language of each Intended Use, each is indicated for the Stimulation of Healthy Muscles

Comparison of the Subject and Predicate Devices				
Elements of Comparison	**Subject device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Similar/Different**
		offered under prescription given by a physician licensed in the state in which he or she practices.	contraindicated. The work imposed on the muscles by the Compex Wireless USA programs is definitely not suitable for rehabilitation and physiotherapy. The Compex Wireless USA electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can	

Comparison of the Subject and Predicate Devices				
Elements of Comparison	**Subject device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Similar/Different**
			be imposed on the stimulated muscles. The Compex Wireless USA may therefore be considered a technique of muscle training.	
Body Application Areas	Body	Body	Body	Similar
Power Sources	110vac – 240 vac (AC wall plug-In)	110vac – 240 vac (AC wall plug-In)	Lithium Polymer (LiPo) rechargeable batteries	Different - differences do not present different questions of/or effect safety and effectiveness; the similar currents generated by each channel and applied to the patient is isolated from the power source.
Patient Leakage Current	0.05 µA and	0.07 µA	N/A	Similar
Number of Output Modes for Micro current Stimulation	5	3	1	Different - differences do not present different questions of/or effect safety and

Comparison of the Subject and Predicate Devices				
Elements of Comparison	**Subject device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Similar/Different**
				effectiveness; all outputs meet the requirements of the FDA Guidance on Powered Muscle Stimulators.
Number of Channels for Micro current Stimulation	16	6	4	Different - differences do not present different questions of/or effect safety and effectiveness;; all channels are isolated and generate the identical signal, which are similar to the predicates.
Channel Output: Synchronous or Alternating	Synchronous	Synchronous	Synchronous	Similar
Channel Output: Method of Line Current Isolation	Power Supply isolation	Power Supply isolation	Power Supply isolation	Similar
Regulated Current or Regulated Voltage	Both	Voltage	Both	Similar (voltage regulated devices)
Software/Firmware/Microprocessor control	No	No	Yes	Different - differences do not present different questions of/or

Comparison of the Subject and Predicate Devices				
Elements of Comparison	**Subject device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Similar/Different**
				effect safety and effectiveness; the similar currents generated by each unit is not related to software/ firmware.
Automatic Overload Trip	Yes	Yes	Yes	Similar
Automatic No load Trip	Yes	Yes	Yes	Similar
Indicator Display: On / Off Status	Yes	Yes	Yes	Similar
Indicator Display: Voltage Current Level	Yes	Yes	Yes	Similar
Timer Range	None	Yes	Yes	Similar
Compliance with Standards	Electrical Safety: Comply with IEC 60601-1 and IEC 60601-2-10 EMC: Comply with IEC 60601-1-2 Biocompatibility: ISO10993-5 and ISO10993-10	Electrical Safety: Comply with IEC 60601-1 and IEC 60601-2-10 EMC: Comply with IEC 60601-1-2 Biocompatibility: ISO10993-5 and ISO10993-10	Electrical Safety: Comply with IEC 60601-1 and IEC 60601-2-10 EMC: Comply with IEC 60601-1-2 Biocompatibility: Unknown	Similar
Compliance with 21 CFR 898	Yes	Yes	Yes	Similar

Comparison of the Subject and Predicate Devices				
Elements of Comparison	**Subject device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Similar/Different**
Weight	See Section 11 for weight of individual models	12.35 oz	Remote: 3.9 oz Console:2x 2.1 oz Docking Station 28.2 oz	Different - differences do not present different questions of/or effect safety and effectiveness; the similar currents generated by each unit is not related to weight of the unit.
Dimensions	See Section 11 for dimensions of individual models	5.6” x 3.9” x 1.4” (L x W x H)	Remote 3.5”x1.8”x0.28” Console: 2.6”x0.8” Docking Station: 9.8”x9.8”x0.8”	Different - differences do not present different questions of/or effect safety and effectiveness; the similar current generated by each unit is not related to size of the unit.
Housing Materials and Construction	Aluminum	Metal	Plastic	Different - differences do not present different questions of/or effect safety and effectiveness; the similar current generated by each unit is not related to eco user material of the unit.

Comparison of the Subject and Predicate Devices				
Elements of Comparison	**Subject device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Similar/Different**
Additional Information				
Waveform (see Section 18 for details)	Biphasic	Biphasic	Biphasic	Similar
Shape	Rectangular	Rectangular	Rectangular	Similar
Maximum Output Voltage	58V @ 500 Ω 88V @ 2k Ω	50 V @ 500 Ω 200 V @ 10K Ω	60 V @ 500 Ω 180V @ 2 kΩ 180 V @ 10 kΩ	Similar
Maximum Output Current	108 ma at 500 Ω	100 am at 500 Ω	120 mA @ 500 Ω	Similar
Frequency range	200 to 1200 Hz	90 to 120 Hz	1 to 120 Hz	Similar
Pulse width range	500 to 2500 µsec	416 to 500 µsec	300 to 400 µsec	Similar
Net Charge	0 @ 500 Ω Zero net charge is achieved by using symmetrical biphasic waveforms	10000 µColumns @ 500 Ω 4000 µColumns @ 2K Ω 2500 µColumns @ 10K Ω	0 @ 500 Ω	Similar
Maximum Phase Charge	45 µC @ 500 Ω @ 200 Hz	50 µC @ 500 Ω @ 90 and 100 Hz 40 µC @ 500 Ω @ 120 Hz	48 µC @ 500Ω	Similar

Comparison of the Subject and Predicate Devices				
Elements of Comparison	**Subject device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Similar/Different**
Maximum Current Density	5 mA / cm2	4 mA / cm2	1.49 mA/cm2	Similar
Maximum Power Density	0.011 W/cm^2	0.0012 W/cm^2	0.00276 W/cm^2	Similar
Environment for operating	Temperature: Approximately 15 to 40° C	Temperature: Approximately 15 to 40° C	Unknown	Similar
Environment for storage	Temperature: Approximately 20 to 60° C Humidity: Approximately 0 to 88% RH	Temperature: Approximately 20 to 60° C Humidity: Approximately 0 to 88% RH	Unknown	Similar