



Food and Drug Administration
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July 12, 2017

DJO, LLC
Neeta Sharma
Sr. Director, Regulatory Affairs
1430 Decision Street
Vista, California 92081

Re: K170903
Trade/Device Name: Compex Wireless USA
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NUH, NYN
Dated: March 27, 2017
Received: March 28, 2017

Dear Neeta Sharma:

This letter corrects our substantially equivalent letter of June 19, 2017.

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,


Michael J. Hoffmann -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

Indications for Use

510(k) Number (if known)

K170903

Device Name

Compex Wireless USA

Indications for Use (Describe)

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 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 motoneurons of motor nerves (excitations). These excitations of motoneurons 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 be imposed on the stimulated muscles. The Compex Wireless USA may therefore be considered a technique of muscle training.

The Compex Wireless USA TENS is used for:

- temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.
- the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

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

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

The assigned 510(k) number is **K170903**.

Submitted by: DJO, LLC
1430 Decision Street
Vista, CA 92081

Contact Person: Neeta Sharma
Sr. Director, Regulatory Affairs
760-734-3551

Date Summary Prepared: March 27, 2017

Trade Name: Compex® Wireless USA

Classification Name: Powered muscle stimulator (21 CFR 890.5850)
Stimulator, Nerve, Transcutaneous (21 CFR 882.5890)

Product Code: Powered Muscle Stimulator, For Muscle Conditioning – 21 CFR 890.5850;
Product Code NGX; Review Panel: Physical Medicine

Stimulator, Nerve, Transcutaneous, Over-The-Counter- 21 CFR 882.5890;
Product Code NUH; Review Panel: Neurology

Stimulator, Electrical, Transcutaneous, For Arthritis 21 CFR 890.5850;
Product Code NYN (subsequent code); Review Panel: Neurology

Regulatory Class: Class II

Predicate Device: Compex Wireless USA (K143551)
Strive (K153704)

Device Description:

The Compex Wireless USA employs programs for neuromuscular electrical stimulation (NMES) and transcutaneous electrical stimulation (TENS).

TENS (Transcutaneous Electrical Nerve Stimulation) and NMES (NeuroMuscular Electrical Stimulation) target different nerve groups of the body. TENS is specifically targets the sensory nerves, which are responsible for sending pain signals to the brain. NMES targets the muscle itself, specifically through the motor nerves. This allows the NMES machine to create a muscle contraction to recruit more muscle fibers when training; warming up or recovering.

The Compex Wireless USA device stimulates nerve fibers by means of electrical impulses transmitted by electrodes. The electrical pulses generated by the Compex Wireless USA stimulate motor nerves to stimulate a muscular response. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, and total session duration), different types of muscle work can be imposed on the stimulated muscles. The Compex Wireless USA may therefore be considered a technique of muscle training.

The device system is made up of a remote control, 4 stimulation modules, and electrodes, which are stored and shipped within the docking station which is used to recharge the remote and the modules. The docking station is powered by an AC-DC adapter.

The remote control is the interface between the stimulation modules and the user. It sends and receives information to and from the modules via a wireless network. The remote control allows the user to navigate through the user interface (UI), select stimulation program or objectives, set desired options and control the four (4) module intensities independently. The remote control is powered by a rechargeable battery.

The Compex Wireless USA stimulation module set is composed of 4 independent stimulation modules that are controlled via the remote control by a wireless connection. Each module is composed of two “pods” (1 battery “pod” and one stimulation “pod”) linked by an electrical connection (cable). Two proprietary Compex standard snap gel electrodes are also needed to connect each “pod” to the body. The modules are powered by a Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 450 [mAh] battery.

The wireless protocol of the Compex Wireless USA Device is a proprietary design of a Radio-Frequency protocol operating the 2.4 GHz ISM band.

It is used to 1) Send particular information from remote control to stimulation modules (stimulation settings)

2) Send particular information from stimulation modules to remote control, like current stimulation level and stimulation module subsystem status,

3) Transfer binary data to stimulation modules, and

4) Allow synchronization from stimulation modules to remote control clocks.

Indications for Use:

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 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 motoneurons of motor nerves (excitations). These excitations of motoneurons 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 be imposed on the stimulated muscles. The Compex Wireless USA may therefore be considered a technique of muscle training.

Compex Wireless USA as a TENS device is used for:

- temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.
- the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

Programs:

Muscle Stimulation Training Programs: The Compex Wireless USA provides four muscle stimulation training programs: Endurance, Resistance, Strength, and Explosive Strength. They correspond to the type of muscle performance the athlete wishes to improve or maintain. Each of the four training programs offers five different working levels that enable the amount of work to be gradually increased.

Specialized Muscle Training Programs: The Compex Wireless USA also offers five special muscle training programs: Potentiation, Training Recovery, Competition Recovery, Muscle Relaxation, and Pre-Warmup. Their objective is to prepare muscles for explosive motions or to facilitate recovery after active muscle training and competition.

TENS Program: Pain Relief TENS program is to alleviate all types of localized pain. Please note that Pain relief TENS was called “Frequency Modulation (FM)” in the predicate device-Strive.

Programs Specification

Program name	Frequency [Hz]	Contraction duration [s]
Training recovery	From 1 to 9 Hz continuous	
Potentialion	From 1 to 2 Hz continuous	
Competition Recovery	From 1 to 5 Hz continuous	
Pre Warmup	8 Hz continuous	
Endurance	10	9
Explosive strength	104	4.25
Resistance	50	9.25
Strength	75	6.25
Muscle Relaxation	1Hz continuous	
Pain Relief TENS	From 90 to 120 Hz	

Comparison to the Predicate Device:

The similarities and differences between the technology and specifications of the subject device and its predicate devices are reflected below:

Basic Device Characteristics – Comparison with Predicate Devices
Device Comparison Tables

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
510(k) Number	Pending	K143551	K153704	
Device Name, Model	Compex® Wireless USA	Compex® Wireless USA	Strive	
Manufacturer	DJO LLC	DJO LLC	DJO LLC	Similar
Prescription/OTC	OTC	OTC	OTC	Similar
Type of device	A non-implantable, battery powered, hand held, electrical stimulator, used for medical purposes through applying an electrical current to electrodes on a patient's skin	A non-implantable, battery powered, hand held, electrical stimulator, used for medical purposes through applying an electrical current to electrodes on a patient's skin	A non-implantable, battery powered, hand held, electrical stimulator, used for medical purposes through applying an electrical current to electrodes on a patient's skin	Similar
Connection of device to electrodes	Lead wires Stimulation Module is directly connected to the custom Compex female SNAP assembled in the electrode. User Interface (LCD and buttons) is physically separated (Remote Control) and communicates wirelessly with up to four (4) Stimulation Modules.	Lead wires Stimulation Module is directly connected to the custom Compex female SNAP assembled in the electrode. User Interface (LCD and buttons) is physically separated (Remote Control) and communicates wirelessly with up to four (4) Stimulation	Lead wires	Similar

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	Stimulation safety remains fully managed by Stimulation Module electronic circuit itself.	Modules. Stimulation safety remains fully managed by Stimulation Module electronic circuit itself.		
Power Sources	Remote: : Lithium Polymer (LiPo) rechargeable 3.7[V] / $\geq$ 1500[mAh] Stimulation Modules: Lithium Polymer (LiPo) rechargeable 3.7[V] / $\geq$ 450[mAh]	Remote: : Lithium Polymer (LiPo) rechargeable 3.7[V] / $\geq$ 1500[mAh] Stimulation Modules: Lithium Polymer (LiPo) rechargeable 3.7[V] / $\geq$ 450[mAh]	LiPo 250 [mAh] (3.7[V]), not removable	Same as Compex Wireless USA Different from Strive
Method of line current isolation	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Similar
Patient Leakage Current	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Similar
• Normal condition	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Similar
• Single fault condition	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Similar
Number of Output Modes	Two (NMES/TENS)	One (NMES)	Two (2 x TENS)	Different
Number of Output Channels	Four	Four	1, split	Same as Compex Wireless USA Different from Strive
- Synchronous or	Synchronous, but	Synchronous, but	N/A	Same as Compex

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
Alternating?	never 2 channels activated at the same time	never 2 channels activated at the same time		Wireless USA Different from Strive
- Method of Channel Isolation	Each channel is the middle of a H- Bridge. Except when it is activated, each channel is always in high impedance state.	Each channel is the middle of a H- Bridge. Except when it is activated, each channel is always in high impedance state.	N/A	Same as Compex Wireless USA Different from Strive
Regulated Current or Regulated Voltage?	Regulated current (all channels)	Regulated current (all channels)	Regulated Current	Similar
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Similar
Automatic Overload Trip?	Yes	Yes	No	Same as Compex Wireless USA Different from Strive
Automatic No-Load Trip?	Yes	Yes	Yes	Similar
Automatic Shut Off?	“On/Off” switch	“On/Off” switch	“On/Off” switch	Similar
Patient Override Control?	Yes, push on On/Off button directly pause the program	Yes, push on On/Off button directly pause the program	Yes, push on On/Off button directly pause the program	Similar
Indicator Display - On/Off Status?	Yes	Yes	Yes	Similar
- Low Battery?	Yes	Yes	No	Same as Compex Wireless USA

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
				Different from Strive
- Voltage/Current Level?	Yes, unit = [Energy]	Yes, unit = [Energy]	Active/inactive output	Same as Compex Wireless USA Different from Strive
Compliance with 21 CFR 898?	Yes	Yes	Yes	Similar
Weight	- Remote: 110 [g] - Stimulation Module: 2x60 [g] - Docking Station 800 [g]	- Remote: 110 [g] - Stimulation Module: 2x60 [g] - Docking Station 800 [g]	0.99 oz	Same as Compex Wireless USA Different from Strive
Waveform (program per program)	-Endurance: Symmetrical Biphasic -Resistance: Symmetrical Biphasic -Strength : Symmetrical Biphasic -Explosive Strength: Symmetrical Biphasic -Potentiation: Symmetrical Biphasic -Training Recovery (same as Active Recovery): Symmetrical Biphasic -Competition	-Endurance: Symmetrical Biphasic -Resistance: Symmetrical Biphasic -Strength : Symmetrical Biphasic -Explosive Strength: Symmetrical Biphasic -Potentiation: Symmetrical Biphasic -Active Recovery: Symmetrical Biphasic -Recovery Plus:		Same as Compex Wireless USA Different from Strive

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	Recovery (same as Recovery Plus): Symmetrical Biphasic -Pre-Warmup Program: Symmetrical Biphasic -Muscle Relaxation (same as Massage): Symmetrical Biphasic -Pain relief TENS (same as FM): Balanced, asymmetrical Biphasic	Symmetrical Biphasic -Pre-Warmup Program: Symmetrical Biphasic -Massage: Symmetrical Biphasic	Balanced, Asymmetrical Biphasic	Same as Strive Different from Compex Sport Plus
Shape (program per program)	-Endurance: Rectangular -Resistance: Rectangular -Strength : Rectangular -Explosive Strength: Rectangular -Potentiation: Rectangular -Training Recovery: Rectangular	-Endurance: Rectangular -Resistance: Rectangular -Strength : Rectangular -Explosive Strength: Rectangular -Potentiation: Rectangular -Training Recovery: Rectangular		Same as Compex Wireless USA Different from Strive

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	-Competition Recovery: Rectangular -Pre-Warmup: Rectangular -Muscle Relaxation: Rectangular -Pain relief TENS (same as FM):	- Competition Recovery: Rectangular -Pre-Warmup: Rectangular - Muscle Relaxation: Rectangular	Square positive pulse, current controlled Logarithmic negative pulse, decrease current	Same as Strive Different from Compex Wireless USA
Maximum Output Voltage ($\pm 10\%$)	<u>Endurance:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Resistance:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Strength:</u> 60 V @ 500 Ω	<u>Endurance:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Resistance:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Strength:</u> 60 V @ 500 Ω		Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Same as Compex

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	165 V @ 2 kΩ 165 V @ 10 kΩ	165 V @ 2 kΩ 165 V @ 10 kΩ		Wireless USA Different from Strive
	<u>Explosive Strength:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ	<u>Explosive Strength:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ		Same as Compex Wireless USA Different from Strive
	<u>Potentialtion:</u> 60 V @ 500 Ω 152 V @ 2 kΩ 136 V @ 10 kΩ	<u>Potentialtion:</u> 60 V @ 500 Ω 152 V @ 2 kΩ 136 V @ 10 kΩ		Same as Compex Wireless USA Different from Strive
	<u>Training Recovery:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ	<u>Training Recovery :</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ		Same as Compex Wireless USA Different from Strive
	<u>Competition Recovery:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ	<u>Competition Recovery:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ		Same as Compex Wireless USA Different from

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	<u>Pre Warmup</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Muscle Relaxation:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Pain Relief TENS:</u> 180[V] peak on 10[k Ω] 170[V] peak on 2[k Ω] 58[V] peak on 500[Ω]	<u>Pre Warmup</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Muscle Relaxation:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω	110[V] peak on 10[k Ω] 110[V] peak on 2[k Ω] 30[V] peak on 500[Ω]	Strive Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Different from Strive and from Compex Wireless USA
Maximum Output Current ($\pm 10\%$)	<u>Endurance:</u> 116 mA @ 500 Ω 80 mA @ 2 k Ω 15 mA @ 10 k Ω	<u>Endurance:</u> 120 mA @ 500 Ω 84 mA @ 2 k Ω 14 mA @ 10 k Ω		Same as Compex Wireless USA Different from Strive

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	<u>Resistance:</u> 116 mA @ 500 Ω 80 mA @ 2 kΩ 17 mA @ 10 kΩ <u>Strength:</u> 113 mA @ 500 Ω 80 mA @ 2 kΩ 15 mA @ 10 kΩ <u>Explosive Strength:</u> 81 mA @ 500 Ω 81 mA @ 2 kΩ 15 mA @ 10 kΩ <u>Potential:</u> 117 mA @ 500 Ω 80 mA @ 2 kΩ 16 mA @ 10 kΩ	<u>Resistance:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 17 mA @ 10 kΩ <u>Strength:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 18 mA @ 10 kΩ <u>Explosive Strength:</u> 84 mA @ 500 Ω 82 mA @ 2 kΩ 18 mA @ 10 kΩ <u>Potential:</u> 120 mA @ 500 Ω 76 mA @ 2 kΩ 13 mA @ 10 kΩ		Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	<u>Training Recovery:</u> 116 mA @ 500 Ω 81mA @ 2 k Ω 16 mA @ 10 k Ω	<u>Active Recovery:</u> 120 mA @ 500 Ω 83 mA @ 2 k Ω 18 mA @ 10 k Ω		Same as Compex Wireless USA Different from Strive
	<u>Competition Recovery:</u> 116 mA @ 500 Ω 81 mA @ 2 k Ω 16 mA @ 10 k Ω	<u>Competition Recovery:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 18 mA @ 10 k Ω		Same as Compex Wireless USA Different from Strive
	<u>Pre Warmup</u> 116 mA @ 500 Ω 81 mA @ 2 k Ω 15 mA @ 10 k Ω	<u>Pre Warmup</u> 120 mA @ 500 Ω 83 mA @ 2 k Ω 18 mA @ 10 k Ω		Same as Compex Wireless USA Different from Strive
	<u>Muscle Relaxation:</u> 116 mA @ 500 Ω 81 mA @ 2 k Ω 16 mA @ 10 k Ω	<u>Muscle Relaxation:</u> 120 mA @ 500 Ω 80mA @ 2 k Ω 16 mA @ 10 k Ω		Same as Compex Wireless USA Different from Strive
	<u>Pain Relief TENS:</u> 18[mA] peak @10[k Ω] 86[mA] peak@2[k Ω]		12[mA] peak @10[k Ω] 55[mA] peak@2[k Ω] 60[mA] peak@500[Ω]	Different from Strive and from Compex

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	116[mA] peak@500[Ω]			Wireless USA
Pulse Width	<u>Endurance:</u> 200 to 400 [μs] <u>Resistance:</u> 200 to 400 [μs] <u>Strength:</u> 200 to 400 [μs] <u>Explosive Strength:</u> 200 to 400 [μs] <u>Potential:</u> 200 to 400 [μs]	<u>Endurance:</u> 200 to 400 [μs] <u>Resistance:</u> 200 to 400 [μs] <u>Strength:</u> 200 to 400 [μs] <u>Explosive Strength:</u> 200 to 400 [μs] <u>Potential:</u> 200 to 400 [μs]		Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	<u>Training Recovery:</u> 200 to 400 [μs]	<u>Training Recovery:</u> 200 to 400 [μs]		Same as Compex Wireless USA Different from Strive
	<u>Competition Recovery:</u> 200 to 400 [μs]	<u>Competition Recovery:</u> 200 to 400 [μs]		Same as Compex Wireless USA Different from Strive
	<u>Pre Warmup</u> 200 to 400 [μs]	<u>Pre Warmup</u> 200 to 400 [μs]		Same as Compex Wireless USA Different from Strive
	<u>Muscle Relaxation:</u> 200 to 400 [μs]	<u>Muscle Relaxation:</u> 200 to 400 [μs]		Same as Compex Wireless USA Different from Strive
	<u>Pain Relief TENS:</u> 70 to 300[μs] (measured at 50% of positive pulse)		70 to 300[μs] (measured at 50% of positive pulse)	Same as Strive, different from Compex Wireless USA

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
Frequency	<u>Endurance:</u> 10 [Hz] <u>Resistance:</u> 50 [Hz] <u>Strength:</u> 75 [Hz] <u>Explosive Strength:</u> 100 [Hz] <u>Potential:</u> From 1 to 75 [Hz]	<u>Endurance:</u> 10 [Hz] <u>Resistance:</u> 50 [Hz] <u>Strength:</u> 75 [Hz] <u>Explosive Strength:</u> 100 [Hz] <u>Potential:</u> From 1 to 75 [Hz]		Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive Same as Compex Wireless USA Different from Strive

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	<u>Training Recovery:</u> 10 [Hz]	<u>Training Recovery:</u> 10 [Hz]		Same as Compex Wireless USA Different from Strive
	<u>Competition Recovery:</u> 0.5 [Hz]	<u>Competition Recovery:</u> 0.5 [Hz]		Same as Compex Wireless USA Different from Strive
	<u>Pre Warmup</u> 4 [Hz]	<u>Pre Warmup</u> 4 [Hz]		Same as Compex Wireless USA Different from Strive
	<u>Muscle Relaxation:</u> 1 [Hz]	<u>Muscle Relaxation:</u> 1 [Hz]		Same as Compex Wireless USA Different from Strive
	<u>Pain Relief TENS:</u> 5 to 122[Hz]		5 to 122[Hz]	Same as Strive, different from Compex Wireless USA

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
Net Charge [μC /pulse]	<u>Endurance:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated	<u>Endurance:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated		Same as Compex Wireless USA Different from Strive
	<u>Resistance:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated	<u>Resistance:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated		Same as Compex Wireless USA Different from Strive
	<u>Strength:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated	<u>Strength:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated		Same as Compex Wireless USA Different from Strive
	<u>Explosive Strength:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated	<u>Explosive Strength:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated		Same as Compex Wireless USA Different from Strive
	<u>Potentialion:</u> 0 [μC] @ 500 Ω Excitation pulse fully	<u>Potentialion:</u> 0 [μC] @ 500 Ω Excitation pulse fully		Same as Compex Wireless USA

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	compensated	compensated		Different from Strive
	<u>Training Recovery:</u> 0 [μC] @ 500Ω Excitation pulse fully compensated	<u>Training Recovery:</u> 0 [μC] @ 500Ω Excitation pulse fully compensated		Same as Compex Wireless USA Different from Strive
	<u>Competition Recovery:</u> 0 [μC] @ 500Ω Excitation pulse fully compensated	<u>Competition Recovery:</u> 0 [μC] @ 500Ω Excitation pulse fully compensated		Same as Compex Wireless USA Different from Strive
	<u>Pre Warmup</u> 0 [μC] @ 500Ω Excitation pulse fully compensated	<u>Pre Warmup</u> 0 [μC] @ 500Ω Excitation pulse fully compensated		Same as Compex Wireless USA Different from Strive
	<u>Muscle Relaxation:</u> 0 [μC] @ 500Ω Excitation pulse fully compensated	<u>Muscle Relaxation:</u> 0 [μC] @ 500Ω Excitation pulse fully compensated		Same as Compex Wireless USA Different from Strive

Basic Unit Characteristics – Comparison with Predicate Device				
Characteristic	New Device	Predicate Device	Predicate Device	Similar/ Different
	<u>Pain Relief TENS:</u> 0 [μC] @ 500Ω Excitation pulse fully compensated		18[uC] on 1[kΩ]	Different from Compex Wireless USA and Strive
Maximum Phase Charge [μC]	48 [μC] @ 500Ω <i>See detailed math below*</i>	48 [μC] @ 500Ω	0[uC] on 1[kΩ]	Same as Compex Wireless USA Different from Strive
Maximum Current Density [mA/cm ²]	4.8 [mA/cm ²] @ 500Ω <i>See detailed math below*</i>	4.8 [mA/cm ²] @ 500Ω	0.31[mA/cm ²] (over 1[s] period)	Same as Compex Wireless USA Different from Strive
Maximum Power Density [mW/cm ²]	27.6 [mW/cm ²] @ 500Ω <i>See detailed math below*</i>	27.6 [mW/cm ²] @ 500Ω	4.92[mW/cm ²] (split on 2x1[kΩ] in //)	Same as Compex Wireless USA Different from Strive

Although there are minor differences observed between the subject device and the predicate devices, those differences do not raise any question in regards to safety and effectiveness.

Performance Testing:

Electrical Safety and Electromagnetic Compatibility: The Compex Wireless USA was tested and found to comply with the following standards for electrical safety and electromagnetic compatibility.

FCC Radio Frequency Testing: The Compex Wireless USA was tested to FCC requirements and found to comply with the requirements of 47 CFR 15.249.

Software Verification: The device's software was verified in accordance with the requirements of FDA's guidance document: General Principles of Software Validation, January 11, 2002. The software testing demonstrated that the software meets its design requirements.

Usability/Human Factors Testing: Usability/Human Factors testing was performed, which demonstrated that the established requirements for usability were met, and the device's design is appropriate for the intended users and use environment. The result of this study substantiates the acceptability of the use-related risks identified during the risk assessment activities.

Wireless Coexistence Testing: The performance of Compex Wireless USA was evaluated in an environment with other Compex Wireless USA device and with other types of 2.4 GHz wireless devices (Bluetooth and Wi-Fi). The device met all specified requirements.

Standards:

The Compex Wireless USA conforms to the following standards:

- AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1, Mod.). FDA Recognition No. 19-4.
- IEC 60601-1-2 Edition 3:2007-03, Medical Electrical Equipment - Part 1 -2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests. FDA Recognition No. 19-1.
- IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability. FDA Recognition No. 5-89.
- IEC 60601-1-11 Edition 1.0 2010-04, Medical Electrical Equipment - Part 1-11: General Requirements - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment. FDA Recognition No. 19-6.

- IEC 60601-2-10 Edition 2.0 2012-06, Medical Electrical Equipment - Part 2-10: Particular Requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators. FDA Recognition No. 17-11.
- IEC 62366 Edition 1.1 2014-01 , Consolidated Version Medical Devices - Application Of Usability Engineering To Medical Devices. (General I (QS/RM)). FDA Recognition No. 5-87
- ISO 14971 Second Edition 2007-03-01. Medical Devices - Applications of Risk Management to Medical Devices. Recognition No. 5-40.
- AAMI /ANSI /IEC 62304:2006, Medical Device Software - Software Life Cycle Processes. Recognition No. 13-32.

This submission does not contain clinical data.

Conclusion:

Based on the performance testing and the similarities of the indications for use and the technological characteristics, it can be concluded that the Compex Wireless USA is as safe and effective as, and substantially equivalent to, the predicate devices.