



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

June 20, 2017

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

Re: K170918
Trade/Device Name: Compex Sport Elite
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NUH, NYN
Dated: March 28, 2017
Received: March 29, 2017

Dear Neeta Sharma:

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,

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)

K170918

Device Name

Compex Sport Elite

Indications for Use (Describe)

EMS: The Compex Sport Elite is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the Compex Sport Elite programs is not suitable for rehabilitation or physiotherapy.

TENS: The Compex Sport Elite TENS is intended for:

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

The Compex® Sport Elite is an Over-The-Counter device to be used by adults only.

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 **K170918**.

Submitted by: DJO, LLC
1430 Decision Street
Vista, CA 92081
FDA Establishment Registration: 2020737

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

Date Summary Prepared: June 19, 2017

Trade Name: Compex® Sport Elite

Classification Name: Stimulator, muscle, powered (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 (primary product code)

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 Sport Plus (K083140) - Class II (primary predicate device)
Strive (K153704) - Class II

Device Description:

The Compex® Sport Elite is an electrical stimulation device, which stimulates healthy muscles by means of electrical impulses transmitted by electrodes. The electrical pulses generated by the Compex® Sport Elite 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® Sport Elite may therefore be considered a technique of muscle training.

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® Sport Elite system consists of these components:

- 1x Stimulator
- 1x Lead Wire Set
- 2x Small Performance Snap Electrode package
- 2x Large Performance Snap Electrode package
- 1x Battery Charger

These components are packaged together in a carrying case along with the user guide and a battery charger.

The stimulator is a microprocessor controlled 4 channels electro-stimulator. The stimulator drives each output channel independently based upon the parameters pre-defined for a program selected by the user. The user operates the device through a User Interface (UI) consisting of a graphic LCD, keypad controls and supporting software. The User Interface is made up of different menus that allow the following functions: set up the device (Options Menu), select a desired category (Category Menu), select a preset program (Treatments' Menu), tune a selected program (Stimulation Menu), and adjust the stimulation intensities (Level Menu).

Indications for Use:

The Compex Sport Elite EMS is used for:

The Compex Sport Elite is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

The work imposed on the muscles by the Compex Sport Elite programs is definitely not suitable for rehabilitation and physiotherapy.

The Compex Sport Elite TENS is intended 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.

The Compex Sport Elite is an Over-the-Counter device to be used by adults only.

Comparison to the Predicate Device:

The indications for use for the Compex® Sport Elite are similar to those of the predicate devices, Compex Sport Plus (K083140) and Strive (K153704).

The technological characteristics of the predicate devices are very similar, but there are a few minor differences.

Device Comparison Tables

	Basic Unit Characteristics – Comparison with Predicate Device				
	Characteristic	New Device	Predicate Device	Predicate Device	Similar/Different
1	510(k) Number	Pending	K083140	K153704	
2	Device Name, Model	Compex Sport Elite	Compex Sport Plus	Strive	
3	Manufacturer	DJO, LLC	DJO LLC 510(k) sponsor: Chattanooga Group	DJO, LLC	Similar
4	Prescription/OTC	OTC	OTC	OTC	Similar
5	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
6	Indications for Use	The Compex Sport Elite EMS is used for: The Compex Sport Elite is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the Compex Sport Elite programs is definitely	The Compex Sport Elite is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Compex Sport Elite is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the Compex Sport Elite	Over the Counter Use: The Strive™ 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	NMES -Indication for use are the same as Compex Sport Plus device and TENS- Indication for use are the same as Strive

		not suitable for rehabilitation and physiotherapy. The Compex Sport Elite TENS is intended 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. The Compex Sport Elite is an Over-the-Counter device to be used by adults only.	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 Sport Elite programs is definitely not suitable for rehabilitation and physiotherapy. The Compex Sport Elite 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,	and management of chronic, intractable pain and relief of pain associated with arthritis.	
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			duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. The Compex Sport Elite may therefore be considered a technique of muscle training.		
7	Connection of device to electrodes	Lead wires With 6-pole cables including female custom SNAP plugged on the custom Compex female SNAP assembled in the electrode. Entire electronic circuit for four (4) Stimulation Channels and User Interface is combined into same casing, connected to the electrodes with 6-pole cables.	Lead wires With 6-pole cables including female custom SNAP plugged on the custom Compex female SNAP assembled in the electrode. Entire electronic circuit for four (4) Stimulation Channels and User Interface is combined into same casing, connected to the electrodes with 6-pole cables.	Lead wires	Similar
8	Power Sources	Rechargeable Ni-Mh Battery 4.8V (4 cells AA=R6)	Rechargeable Ni-Mh Battery 4.8V (4 cells AA=R6)	LiPo 250 [mAh] (3.7[V]), not removable	Same as Compex Sport Plus 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
9	Number of Output Modes	Two (NMES/TENS)	One (NMES)	Two (2 x TENS)	Different
10	Number of Output Channels	Four	Four	1, split	Same as Complex Sport Plus Different from Strive
	- Synchronous or Alternating?	Synchronous, but never 2 channels activated at the same time	Synchronous, but never 2 channels activated at the same	N/A	Same as Complex Sport Plus 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 Complex Sport Plus Different from Strive
11	Regulated Current or Regulated Voltage?	Regulated current (all channels)	Regulated current (all channels)	Regulated Current	Similar
12	Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Similar
13	Automatic Overload Trip?	Yes	Yes	No	Same as Complex Sport Plus Different from Strive
14	Automatic No-Load Trip?	Yes	Yes	Yes	Similar
15	Automatic Shut Off?	“On/Off” switch	“On/Off” switch	“On/Off” switch	Similar

16	Patient Override Control?	Yes	Yes	No	Same as Complex Sport Plus Different from Strive
17	Indicator Display - On/Off Status?	Yes	Yes	Yes	Similar
	- Low Battery?	Yes	Yes	No	Same as Complex Sport Plus Different from Strive
	- Voltage/Current Level?	Yes, unit = [Energy]	Yes, unit = [Energy]	Active/inactive output	Same as Complex Sport Plus Different from Strive
18	Timer Range (minutes)	Yes, unit= [seconds], max = 55 [minutes]	Yes, unit= [seconds], max = 55 [minutes]	Unlimited	Same as Complex Sport Plus Different from Strive
19	Compliance with Voluntary Standards?	Yes -IEC 60601-1 -IEC 60601-1-2 -IEC 60601-1-6 -IEC 60601-2-10 -IEC60601-1-11 -IEC 62366 -IEC 62304	Yes -IEC 60601-1 -IEC 60601-1-2 -IEC 60601-1-4 -IEC 60601-2-10	Yes -IEC 60601-1 -IEC 60601-1-2 -IEC 60601-1-11 -IEC 60601-2-10 -IEC 60601-1-6	Different
20	Compliance with 21CFR 898?	Yes	Yes	Yes	Similar
21	Weight	300 [g]	300 [g]	0.99 oz	Same as Complex Sport Plus Different from Strive
22	Dimensions [W x H x D]	99 x 142 x 36 [mm] 3.9 x 5.6 x 1.4 [in]	99 x 142 x 36 [mm] 3.9 x 5.6 x 1.4 [in]	49 mm x 64mm x 14 mm	Same as Complex Sport Plus

					Different from Strive
23	Housing Materials and Construction	Casing: Plastic (ABS, with PMMA on the windows) Buttons: Silicon rubber Battery Pack: Rigid ABS housing around the battery cells Battery contacts: SK5 steel	Casing: Plastic (ABS, with PMMA on the windows) Buttons: Silicon rubber Battery Pack: Rigid ABS housing around the battery cells Battery contacts: SK5 steel	Casing: Plastic (ABS+PC) Buttons: silicons rubber	Similar
24	Programs	- Endurance - Resistance - Strength - Explosive Strength - Potentiation - Training Recovery (same as Active Recovery) - Competition Recovery (same as Recovery Plus) - Pre-Warmup Program - Muscle Relaxation (same as Massage) -Pain relief TENS (same as FM)	- Endurance - Resistance - Strength - Explosive Strength - Potentiation - Active Recovery - Recovery Plus - Pre-Warmup - Massage	Frequency Modulation (FM) and SMP	Different

25	Electrodes	Article number : 11-9119 11-9120	Article number : 11-9119 11-9120	Article number: 6250900	Same as Sport Plus Different from Strive
Output Specifications – Comparison with Predicate Device					
	Characteristic	New Device	Predicate Device	Predicate Device	Similar/Different
1	510(k) Number	Pending	K083140	K153704	
2	Device Name, Model	Compex Sport Elite	Compex Sport Plus	Strive	
3	Manufacturer	DJO, LLC	DJO, LLC 510(k) sponsor: Chattanooga Group	DJO, LLC	Similar
4	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 Recovery (same as Recovery Plus): Symmetrical Biphasic -Pre-Warmup Program: Symmetrical	-Endurance: Symmetrical Biphasic -Resistance: Symmetrical Biphasic -Strength : Symmetrical Biphasic -Explosive Strength: Symmetrical Biphasic -Potentiation: Symmetrical Biphasic -Active Recovery: Symmetrical Biphasic -Recovery Plus: Symmetrical Biphasic -Pre-Warmup Program: Symmetrical Biphasic -Massage: Symmetrical Biphasic		Same as Compex Sport Plus Different from Strive

		-Pain relief TENS (same as FM):			Different from Compex Sport Plus
6	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 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Explosive Strength:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Potentiation:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Training Recovery:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k 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 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Explosive Strength:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Potentiation:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω <u>Training Recovery:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k Ω		Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive

		<u>Competition Recovery:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k 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 <u>Pain Relief TENS:</u> 165[V] peak on 10[k Ω] 152[V] peak on 2[k Ω] 60[V] peak on 500[Ω]	<u>Competition Recovery:</u> 60 V @ 500 Ω 165 V @ 2 k Ω 165 V @ 10 k 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]	Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Different from Strive and from Compex Sport Plus
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7	Maximum Output Current ($\pm 10\%$)	<u>Endurance:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Resistance:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Strength:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Explosive Strength:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Potentiation:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Training Recovery:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Competition Recovery:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω	<u>Endurance:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Resistance:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Strength:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Explosive Strength:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Potentiation:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Training Recovery:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω <u>Competition Recovery:</u> 120 mA @ 500 Ω 82 mA @ 2 k Ω 16 mA @ 10 k Ω	Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive
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		16 mA @ 10 kΩ <u>Pre Warmup</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>Muscle Relaxation:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>Pain Relief TENS:</u> 12[mA] peak @10[kΩ] 76[mA] peak@2[kΩ] 119[mA] peak@500[Ω]	<u>Pre Warmup</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>Muscle Relaxation:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ	12[mA] peak @10[kΩ] 55[mA] peak@2[kΩ] 60[mA] peak@500[Ω]	Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Different from Strive and from Compex Sport Plus
8	Pulse Width	<u>Endurance:</u> 200 to 400 [μs] <u>Resistance:</u> 200 to 400 [μs]	<u>Endurance:</u> 200 to 400 [μs] <u>Resistance:</u> 200 to 400 [μs]		Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus

		<u>Strength:</u> 200 to 400 [μs]	<u>Strength:</u> 200 to 400 [μs]		Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive
		<u>Explosive Strength:</u> 200 to 400 [μs]	<u>Explosive Strength:</u> 200 to 400 [μs]		
		<u>Potentiation:</u> 200 to 400 [μs]	<u>Potentiation:</u> 200 to 400 [μs]		
		<u>Training Recovery:</u> 200 to 400 [μs]	<u>Training Recovery:</u> 200 to 400 [μs]		
		<u>Competition Recovery:</u> 200 to 400 [μs]	<u>Competition Recovery:</u> 200 to 400 [μs]		
		<u>Pre Warmup</u> 200 to 400 [μs]	<u>Pre Warmup</u> 200 to 400 [μs]		
		<u>Muscle Relaxation:</u> 200 to 400 [μs]	<u>Muscle Relaxation:</u> 200 to 400 [μs]		
		<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)	Different from Strive

					Same as Compex Sport Plus Different from Strive Same as Strive, different from Compex Sport Plus
9	Frequency	<u>Endurance:</u> 10 [Hz] <u>Resistance:</u> 50 [Hz] <u>Strength:</u> 75 [Hz] <u>Explosive Strength:</u> 100 [Hz] <u>Potentiation:</u> From 1 to 75 [Hz] <u>Training Recovery:</u> 10 [Hz] <u>Competition Recovery:</u> 0.5 [Hz] <u>Pre Warmup</u>	<u>Endurance:</u> 10 [Hz] <u>Resistance:</u> 50 [Hz] <u>Strength:</u> 75 [Hz] <u>Explosive Strength:</u> 100 [Hz] <u>Potentiation:</u> From 1 to 75 [Hz] <u>Training Recovery:</u> 10 [Hz] <u>Competition Recovery:</u> 0.5 [Hz] <u>Pre Warmup</u> 4 [Hz]		Same as Compex Sport Plus Different from Strive

		4 [Hz] <u>Muscle Relaxation:</u> 1 [Hz] <u>Pain Relief TENS:</u> 5 to 122[Hz]	<u>Muscle Relaxation:</u> 1 [Hz]	5 to 122[Hz]	Same as Strive, different from Compex Sport Plus
10	For interferential modes only: - Beat Frequency [Hz]	N/A	N/A	N/A	Similar
11	For multiphasic waveforms only: - Symmetrical phases? Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	<u>Endurance:</u> Symmetrical, 280 - 400 μ s <u>Resistance:</u> Symmetrical, 280 - 400 μ s <u>Strength:</u> Symmetrical, 280 - 400 μ s <u>Explosive Strength:</u> Symmetrical, 280 - 400 μ s	<u>Endurance:</u> Symmetrical, 280 - 400 μ s <u>Resistance:</u> Symmetrical, 280 - 400 μ s <u>Strength:</u> Symmetrical, 280 - 400 μ s <u>Explosive Strength:</u> Symmetrical, 280 - 400 μ s		Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive

		<u>Potentiation:</u> Symmetrical, 280 - 400 μ s <u>Training Recovery:</u> Symmetrical, 280 - 400 μ s <u>Competition Recovery:</u> Symmetrical, 280 - 400 μ s <u>Pre Warmup</u> Symmetrical, 280 - 400 μ s <u>Muscle Relaxation:</u> Symmetrical, 280 - 400 μ s <u>Pain Relief TENS:</u> Symmetrical, 70 - 300 μ s	<u>Potentiation:</u> Symmetrical, 280 - 400 μ s <u>Training Recovery:</u> Symmetrical, 280 - 400 μ s <u>Competition Recovery:</u> Symmetrical, 280 - 400 μ s <u>Pre Warmup</u> Symmetrical, 280 - 400 μ s <u>Muscle Relaxation:</u> Symmetrical, 280 - 400 μ s	Biphasic: - Asymmetrical - 70 to 300[μ s] for positive pulse, logarithmic negative pulse, decrease current.	Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive
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					Different from Compex Sport Plus and Strive
12	Net Charge [μC /pulse]	<u>Endurance:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated <u>Resistance:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated <u>Strength:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated <u>Explosive Strength:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated <u>Potentiation:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated	<u>Endurance:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated <u>Resistance:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated <u>Strength:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated <u>Explosive Strength:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated <u>Potentiation:</u> 0 [μC] @ 500 Ω Excitation pulse fully compensated		Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive Same as Compex Sport Plus Different from Strive

		<u>Training Recovery:</u> 0 [μ C] @ 500 Ω Excitation pulse fully compensated	<u>Training Recovery:</u> 0 [μ C] @ 500 Ω Excitation pulse fully compensated		Same as Compex Sport Plus Different from Strive
		<u>Competition Recovery:</u> 0 [μ C] @ 500 Ω Excitation pulse fully compensated	<u>Competition Recovery:</u> 0 [μ C] @ 500 Ω Excitation pulse fully compensated		Same as Compex Sport Plus Different from Strive
		<u>Pre Warmup</u> 0 [μ C] @ 500 Ω Excitation pulse fully compensated	<u>Pre Warmup</u> 0 [μ C] @ 500 Ω Excitation pulse fully compensated		Same as Compex Sport Plus Different from Strive
		<u>Muscle Relaxation:</u> 0 [μ C] @ 500 Ω Excitation pulse fully compensated	<u>Muscle Relaxation:</u> 0 [μ C] @ 500 Ω Excitation pulse fully compensated		Same as Compex Sport Plus Different from Strive
		<u>Pain Relief TENS:</u> 0 [μ C] @ 500 Ω Excitation pulse fully compensated		18[uC] on 1[k Ω]	

					Different from Compex Sport Plus and Strive
13	Maximum Phase Charge [μC]	48 [μC] @ 500 Ω	48 [μC] @ 500 Ω	0[uC] on 1[k Ω]	Same as Compex Sport Plus Different from Strive
14	Maximum Current Density [mA/cm ²]	4.8 [mA/cm ²] @ 500 Ω	4.8 [mA/cm ²] @ 500 Ω	0.31[mA/cm ²] (over 1[s] period)	Same as Compex Sport Plus Different from Strive
15	Maximum Power Density [mW/cm ²]	27.6 [mW/cm ²] @ 500 Ω	27.6 [mW/cm ²] @ 500 Ω	4.92[mW/cm ²] (split on 2x1[k Ω] in //)	Same as Compex Sport Plus Different from Strive
16	Burst Mode (i.e. pulse trains) a) Pulses per burst b) Bursts per second c) Burst duration (seconds) Duty Cycle [Line (b) x Line (c)]	N/A, no burst mode	N/A, no burst mode	N/A, no burst mode	Similar
17	ON Time (seconds)	Depends on the selected program	Depends on the selected program	Once started, the output is active until user manually stops the unit	Same as Compex Sport Plus Different from Strive

18	OFF Time (seconds)	Depends on the selected program	Depends on the selected program	N/A, no OFF time	Same as Compex Sport Plus Different from Strive
19	Additional Features (if applicable)	N/A	N/A	N/A	Similar

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 Sport Plus was tested and found to comply with the following standards for electrical safety and electromagnetic compatibility.

- IEC 60601-1 for basic safety and essential performance
- IEC 60601-1-2 for electromagnetic compatibility
- IEC 60601-1-11 for use in a home healthcare environment
- IEC 60601-2-10 for performance of nerve and muscle stimulators

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. DJO, LLC establish design inputs for the devices related to cybersecurity, and establish a cybersecurity vulnerability and management approach as part of the software validation and risk analysis that is required by 21 CFR 820.30(g).

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.

Standards:

The Compex Sport Plus 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 2.0 2015-01, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment . (General II (ES/EMC)). FDA Recognition No. 19-14.
- 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. FDA Recognition No. 5-40.
- AAMI /ANSI /IEC 62304:2006, Medical Device Software - Software Life Cycle Processes. FDA Recognition No. 13-32.

This submission does not contain clinical data.

Conclusion:

Based on the performance testing and the technological characteristics, it can be concluded that the Compex Sport Elite is as safe and effective as, and substantially equivalent to, the predicate devices.