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April 14, 2016

DJO, LLC  
Lorri Trotter  
Regulatory Affairs Manager  
1430 Decision Street  
Vista, California 92081

Re: K153696  
Trade/Device Name: Chattanooga Revolution Wireless  
Regulation Number: 21 CFR 890.5850  
Regulation Name: Powered Muscle Stimulator  
Regulatory Class: Class II  
Product Code: IPF; GZJ  
Dated: March 11, 2016  
Received: March 14, 2016

Dear Ms. Trotter:

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)

K153696

Device Name

Chattanooga Revolution Wireless

Indications for Use (Describe)

The Chattanooga Revolution Wireless is a clinical electrotherapy device intended for use under the supervision of a Healthcare Professional.

Indications for Use:

As an NMES device, indications are for the following conditions:

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasms
- Increasing local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

As a TENS device, indications are for the following conditions:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical and post-trauma acute pain

As a pulsed mode device, indications are for the following conditions:

- Relaxation of muscle spasm
- Increasing local blood circulation
- Retardation or prevention of disuse atrophy
- Maintenance or increase of range of motion

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

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

**Contact Person:** Lorri Trotter  
Regulatory Affairs Manager  
(760)734-3049

**Date Summary Prepared:** April 11, 2016

**Trade Name:** Chattanooga<sup>®</sup> Revolution Wireless

**Classification Name:** Powered muscle stimulator (21 CFR 890.5850);  
Transcutaneous electrical nerve stimulator for pain relief  
(21 CFR 5890)

**Product Code:** IPF, GZJ

**Regulatory Class:** Class II

**Predicate Device:** Vectra Neo (K132284)

### Device Description:

The Chattanooga<sup>®</sup> Revolution Wireless is a neuromuscular electrical stimulation (NMES) device, which stimulates nerve fibers by means of electrical impulses transmitted by electrodes. The electrical pulses generated by the Chattanooga<sup>®</sup> Revolution Wireless 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 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 Chattanooga<sup>®</sup> Revolution Wireless 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 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] /  $\geq 450$  [mAh] battery.

The docking station is the part on which all the other components (modules, remote and accessories) are stored when the Chattanooga Revolution Wireless system is not in use. The docking is continuously connected to an AC wall socket and it allows charging simultaneously the 4 stimulation modules and the remote control. The docking main part is intended to be fixed and not for transportation purposes, but the tablet may be removed and used as a portable charging station for the remote and modules. The docking station includes a removable tray where the user can store electrodes, quick start guide, the remote and modules for transportation.

The wireless protocol of the Chattanooga<sup>®</sup> Revolution Wireless 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 Chattanooga Revolution Wireless is a clinical electrotherapy device intended for use under the supervision of a Healthcare Professional.

#### Indications for Use:

As an NMES device, indications are for the following conditions:

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasms
- Increasing local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

As a TENS device, indications are for the following conditions:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical and post-trauma acute pain

As a pulsed mode device, indications are for the following conditions:

- Relaxation of muscle spasm
- Increasing local blood circulation
- Retardation or prevention of disuse atrophy
- Maintenance or increase of range of motion

### **Programs:**

The Chattanooga Revolution Wireless provides 14 programs: Trigger Point, Acute Pain, Chronic Pain, Muscle Pump Cycle, Muscle Pump Continuous, Increase ROM (Range of Motion), Decrease Muscle Tone, Fast Twitch Function, Muscle Atrophy, Slow Twitch Function, VMS-FR Dynamic 2 Channel, VMS-FR Dynamic 4 Channel, VMS-FR Static 2 Channel, and VMS-FR Static 4 Channel.

**Comparison to the Predicate Device: Includes Table**

The indications for use for the Revolution Wireless USA are a subset of those for the predicate device the Vectra Neo Clinical Therapy System. The predicate device has additional features, functions, and applications that are not included in the Revolution Wireless. Therefore, we are comparing the Revolution Wireless only to those functions of the predicate that are applicable.

The technological characteristics of the two devices are very similar for the comparable functions, but there are a few differences. The following table summarizes the similarities and differences between the technological characteristics of the two devices. The power sources of the two devices differ (Revolution is battery powered) and output specifications differ slightly between the two devices, but the Chattanooga Revolution Wireless conforms to required standards, and small differences in output do not raise any issues of safety or effectiveness. The Revolution Wireless differs from the predicate in that it communicates wirelessly with the stimulation modules, but the design of the wireless feature is identical to that of the Compex Wireless USA (k143551).

**Basic Device Characteristics – Comparison with Predicate Device**

<b>Characteristic</b>	<b>New Device</b>	<b>Predicate Device</b>	<b>Similar/ Different</b>
510(K) Number		<b>K132284</b>	
Device Name, Model	Chattanooga Wireless PRO	Vectra Neo Clinical Therapy System	Different
Manufacturer	DJO, LLC	DJO, LLC	Similar
Prescription/OTC	Prescription	Prescription	Similar
Where used	Physician office, physical therapy Clinic, Hospital, Nursing Home, Post Acute Care, Chiropractic Clinic	Physician office, physical therapy Clinic, Hospital, Nursing Home, Post Acute Care, Chiropractic Clinic	Similar
Target population	Adult Population	Adult Population	Similar
Anatomical library	Yes	Yes	Similar
Audio Indicator	Yes	Yes	Similar
Connection of device to electrodes	Stimulation Module is directly connected to the custom male SNAP assembled in the electrode. User Interface (LCD and buttons) is physically separated (Remote	With cables including pins to connect to electrodes pins. There is 1 cable per channel with a maximum of 4 channels	Different

<b>Characteristic</b>	<b>New Device</b>	<b>Predicate Device</b>	<b>Similar/ Different</b>
	Control) and communicates wirelessly with up to four (4) stimulation modules. Stimulation safety remains fully managed by Stimulation Module electronic circuit itself.		
Power Source (s)	Rechargeable battery	100-240V~, 2.6-1.0A, 47-63Hz	Different
Method of Line Current Isolation	NA Battery operated device	Independent transformer isolated	Different
Electrical Type	NA Battery operated device	Type BF	Different
Patient Leakage Current - Normal Condition ( $\mu$ A)	NA Battery operated device	<100uA patient leakage	Different
Patient Leakage Current - Single Fault Condition ( $\mu$ A)	NA Battery operated device	<300uA line leakage	Different
Number of Output Modes	Muscle stimulator: Electrodes	Muscle stimulator: Electrodes Ultrasound: applicators EMG:electrodes Laser: applicator	Different
Number of Output Channels	4	0, 2, or 4	Similar
Synchronous or Alternating	See Output Specifications Below	See Output Specifications Below	
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	Through transformers and opto-couplers	Different
Regulated Current or Regulated Voltage (output signals only)	Regulated current on all channels	Configurable for either constant voltage or constant current, see Output Specifications below.	Similar
Software/Firmware/Microprocessor Control	Yes	Yes	Similar
Automatic Overload Trip	Yes	Yes	Similar

<b>Characteristic</b>	<b>New Device</b>	<b>Predicate Device</b>	<b>Similar/ Different</b>
Automatic No-Load Trip	Yes	Yes	Similar
Automatic Shut Off	Yes, On/off switch	Yes	Similar
Patient Override Control	Yes	Yes	Similar
Indicator Display - On/Off Status - Low Battery - Voltage/Current level?	Yes Yes Yes, unit [mili Amps]	Yes No battery Yes, unit [mA]	Similar
Timer Range (Minutes)	Yes, unit [minutes] Max 30 [minutes]	0-60 [minutes]	Different
Compliance with 21 CFR 898?	Yes 21CFR 898- Performance standard for electrode lead wires and patient cables.	21CFR 898- Performance standard for electrode lead wires and patient cables.	Similar
Weight	Remote: 0.24 lbs with battery	Device: 20.7 lbs	Different
	Stimulation Module: 0.11 lbs per module	Module: 1 lbs	Different
	Docking Station: 3 lbs	Device + Cart Accessory: 48.9 lbs	Different
Dimension (in.) [W x H x D]	Remote: 11 x 7 x 2 cm	Device: [15.89 x 20.05 x 15.89]	Different
	Stimulation Module: 2x(6 x 2) cm	Module: [11.12 x 1.43 x 6.34]	Different
	Docking Station tablet: 14x27x3 [cm]	Device + Cart: [23.94 x 52.85 x 26.19]	Different
<b>OUTPUT SPECIFICATIONS</b>			
<b>VMS Symmetrical Biphasic Waveform</b>			
Shape	Rectangular	Rectangular	Similar
Maximum Output Voltage ( $\pm 10\%$ )	60 V @ 500 $\Omega$ 180V @ 2 k $\Omega$ 180 V @ 10 k $\Omega$	57 V @ 500 $\Omega$ 200 V @ 2 k $\Omega$ 100V @ 10 k $\Omega$ (open lead detected above 10[mA])	Different
Maximum Output Current ( $\pm 10\%$ )	120 mA @ 500 $\Omega$ 90 mA @ 2 k $\Omega$ 18 mA @ 10 k $\Omega$	114 mA @ 500 $\Omega$ 100 mA @ 2 k $\Omega$ 10 mA @ 10 k $\Omega$ (open lead detected above 10[mA])	Different
Pulse Width	300 to 400 [ $\mu$ s] (microseconds)	20 to 400 [ $\mu$ s] (microseconds)	Different
Frequency	1 to 100 Hz	1 – 200 [Hz]	Different
Net Charge [ $\mu$ C/pulse]	0 [ $\mu$ C] @ 500 $\Omega$ Excitation pulse fully compensated	0 [ $\mu$ C] @ 500 $\Omega$	Similar

Characteristic	New Device	Predicate Device	Similar/ Different
Maximum Phase Charge [ $\mu\text{C}$ ]	48 [ $\mu\text{C}$ ] @ 500 $\Omega$	45.6 [ $\mu\text{C}$ ] @ 500 $\Omega$	Different
Maximum Current (RMS) Density (mA/cm <sup>2</sup> )	2.1mA/cm <sup>2</sup>	2.4 mA/cm <sup>2</sup>	Different
Maximum Power Density [mW/cm <sup>2</sup> ]	36 [mW/cm <sup>2</sup> ] @ 500 $\Omega$	55 [mW/cm <sup>2</sup> ] @ 500 $\Omega$	Different
ON Time (seconds)	1 – 10 [sec]	1 – 60 [sec]	Different
OFF Time (seconds)	3 – 50 [sec]	1 – 60 [sec]	Different
Additional Features (if applicable) Interphase interval	100 [ $\mu\text{s}$ ] (microseconds)	100 [ $\mu\text{s}$ ] (microseconds)	Similar
<b>VMS-FR Waveform</b>			
Shape	Rectangular	Rectangular	Similar
Maximum Output Voltage ( $\pm 10\%$ )	60 V @ 500 $\Omega$ 180V @ 2 k $\Omega$ 180 V @ 10 k $\Omega$	57 V @ 500 $\Omega$ 200 V @ 2 k $\Omega$ 100V @ 10 k $\Omega$ (open lead detected above 10[mA])	Different
Maximum Output Current ( $\pm 10\%$ )	120 mA @ 500 $\Omega$ 90 mA @ 2 k $\Omega$ 18 mA @ 10 k $\Omega$	114 mA @ 500 $\Omega$ 100 mA @ 2 k $\Omega$ 10 mA @ 10 k $\Omega$ (open lead detected above 10[mA])	Different
Pulse Width	200 to 300 [ $\mu\text{s}$ ] (microseconds)	20 to 400 [ $\mu\text{s}$ ] (microseconds)	Different
Frequency	35 - 80 Hz	20 - 80 [Hz]	Different
Net Charge [ $\mu\text{C}$ /pulse]	0 [ $\mu\text{C}$ ] @ 500 $\Omega$ Excitation pulse fully compensated	0 [ $\mu\text{C}$ ] @ 500 $\Omega$	Similar
Maximum Phase Charge [ $\mu\text{C}$ ]	36 [ $\mu\text{C}$ ] @ 500 $\Omega$	45.6 [ $\mu\text{C}$ ] @ 500 $\Omega$	Different
Maximum Current (RMS) Density (mA/cm <sup>2</sup> )	1.34mA/cm <sup>2</sup>	1.52 mA/cm <sup>2</sup>	Different
Maximum Power Density [mW/cm <sup>2</sup> ]	14.4 [mW/cm <sup>2</sup> ] @ 500 $\Omega$	22 [mW/cm <sup>2</sup> ] @ 500 $\Omega$	Different
Burst Mode (i.e. pulse trains) a) Pulses per burst b) Bursts per second c) Burst duration (seconds) d) Duty Cycle [Line (b) x Line (c)]	N/A, no burst mode	VMS burst	Different
ON Time (seconds)	1 – 10 [sec]	1 – 60 [sec]	Different
OFF Time (seconds)	3 – 50 [sec]	1 – 60 [sec]	Different
Additional Features (if applicable) Interphase interval	100 [ $\mu\text{s}$ ] (microseconds)	100 [ $\mu\text{s}$ ] (microseconds)	Similar

## Performance Testing:

Electrical Safety and Electromagnetic Compatibility: The Chattanooga® Revolution Wireless was tested and found to comply with recognized standards for electrical safety and electromagnetic compatibility.

FCC Radio Frequency Testing: The Chattanooga® Revolution Wireless 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 Chattanooga® Revolution Wireless was evaluated in an environment with other Chattanooga® Revolution Wireless device and with other types of 2.4 GHz wireless devices (Bluetooth and Wi-Fi). The device met all specified requirements.

## Standards:

The Chattanooga Revolution Wireless conforms to the following standards.

Recognition No.	Standard	Description
19-4	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.)
19-1	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
17-11	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
5-85	IEC 60601-1-6 Edition 3.0 2010-01	Medical Electrical Equipment – Part

		1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
N/A*	IEC 62366:2007, Ed. 1  * Ed. 1 was used because it is cited in IEC 60601-1-6 Ed. 3.0.	Medical Devices - Application of Usability Engineering to Medical Devices
13-8	IEC 62304 First Edition 2006-05	Medical Device Software - Software Life Cycle Processes
<b>5-40</b>	<b>ISO 14971:2007</b>	<b>Medical Devices - Application of Risk Management to Medical Devices</b>

**Conclusion:**

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