DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 17, 2016

Djo, LLC
Natalia Shirina
Regulatory Affairs Specialist 3
1430 Decision Street
Vista, California 92081

Re: K153224
Trade/Device Name: VitalStim® Plus Electrotherapy System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, HCC
Dated: January 14, 2016
Received: January 19, 2016

Dear Natalia Shirina:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153224

Device Name
VitalStim® Plus Electrotherapy System

Indications for Use *(Describe)*
For VMS™ - VitalStim Waveforms and sEMG Triggered Stimulation.
Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction

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 K153224.

Submitted by:	DJO, LLC 1430 Decision Street Vista, CA 92081 FDA Establishment Registration: 2020737
Contact Person:	Natalia Shirina Regulatory Affairs Specialist 3 760-734-5534
Date Summary Prepared:	February 8, 2016
Trade Name:	VitalStim® Plus Electrotherapy System
Classification Name:	Stimulator, muscle, powered (21 CFR 890.5850) Device, Biofeedback (21 CFR 882.5050)
Product Code:	IPF, Stimulator, muscle, powered HCC, Device, Biofeedback
Regulatory Class:	Class II
Predicate Device:	VitalStim Experia (K070425) Class II

Device Description:

The VitalStim® Plus Electrotherapy System is a 2 Channel EMG and 4 Channel electrotherapy system used in treating patients with Oropharyngeal Dysphagia and disorders of the head and neck, with Bluetooth connection to PC software.

Indications for Use:

For VMS™ - VitalStim Waveforms and sEMG Triggered Stimulation.

- Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

Intended Uses- VMS™ Waveform

VMS waveform is a square symmetrical biphasic waveform with the application for use on the musculature of the face.
The intended uses are:

Optional application of sEMG biofeedback with Muscle Stimulation VMS TM waveform for prevention or retardation of disuse atrophy, for muscle re-education, and for relaxation of muscle spasms in the treatment of swallowing musculature dysfunction in post-traumatic conditions or after neurological insult with impaired neuromuscular function.

Intended Uses- VitalStim Waveform

VitalStim waveform is a square symmetrical biphasic waveform with interphase interval pulse with the application for use on the swallowing musculature in the anterior portion of the neck.
The intended uses are:
The VitalStim waveform intended uses are muscle re-education of the swallowing musculature in the treatment of dysphagia (swallowing problems) from any etiology except mechanical causes that would need surgical intervention (for instance, obstructing tumors). Non-mechanical causes of dysphagia include: neurological and muscle disorders; cardiovascular accidents; respiratory disorders with swallowing complications; iatrogenic conditions (conditions caused by surgery); fibrosis/stenosis arising from radiation; disuse due to stroke, intubation, or birth-related anoxic injuries; and trauma to the head and neck. This device is a prescription device intended for use by or on the order of a physician or other licensed health professional.

Intended Uses- Surface EMG

sEMG is surface biofeedback for use on the swallowing musculature of the face and/or anterior portion of the neck. The intended uses are:
The sEMG intended uses are surface electromyography biofeedback for relaxation training and muscle re-education.

Technological Comparison to Predicate Devices:

Based on the critical functional characteristics and indications for use, the VitalStim® Plus Electrotherapy System is substantially equivalent to the VitalStim Experia device (K070425). Both are Class II devices, powered muscle stimulator, biofeedback devices, subject to 21 CFR 890.5850 and 21 CFR 882.5050. Both devices are for prescription use only and the indications for use are the same.

The differences between the VitalStim® Plus Electrotherapy System and the predicate devices are considered to be minor by nature. Any differences in technological characteristics are explained in this submission to demonstrate that these differences do not raise new issues of safety and effectiveness.

Basic Device Characteristics – Comparison with Predicate Device

Characteristic	New Device	Predicate Device	Similar/ Different
510(k) Number	K153224	K070425	
Device Name, Model	VitalStim® Plus Electrotherapy System, Model 5923-3	VitalStim Experia, Model 5950	Similar
Manufacturer	DJO, LLC	DJO, LLC 510(k) sponsor: Chattanooga Group	Similar
Type of device	A non-implantable, battery powered, hand held, electrical muscle conditioning device used for the treatment of medical purposes to apply an electrical current to stimulate and re-educate the swallowing musculature (pharyngeal contractions) in the treatment of dysphagia from any etiology except mechanical causes that would need surgical intervention (e.g., obstructing tumors)	A non-implantable, mains powered, desktop, electrical muscle conditioning device used for the treatment of medical purposes to apply an electrical current to stimulate and re-educate the swallowing musculature (pharyngeal contractions) in the treatment of dysphagia from any etiology except mechanical causes that would need surgical intervention (e.g., obstructing tumors)	Similar
Connection of device to electrodes	Lead wires	Lead wires	Similar
Indications for Use	**For VMS™ and VitalStim Waveforms and sEMG Triggered Stimulation.** - Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.	**For VMS™ and VitalStim Waveforms, High Voltage Pulsed Current (HVPC) and sEMG Triggered Stimulation.** - Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.	Similar
Power Source(s)	6V (4x1.5V AA battery cells)	100-240V – 1.3 A Main P. Supply	Different

Characteristic	New Device	Predicate Device	Similar/ Different
VMS™-Square Symmetrical Biphasic	Yes	Yes	Similar
HVPC™-Monophasic Pulsed	No	Yes	Different
VitalStim™- Square Symmetrical Biphasic	Yes	Yes	Similar
Patient Leakage Current: Normal Condition & Single Fault Condition			
Channel 1	<100µA	<100µA	Similar
Channel 2	<100µA	<100µA	Similar
Channel 3	<100µA	<100µA	Similar
Channel 4	<100µA	<100µA	Similar
Number of Output Channels	Four	Four	Similar
Synchronous or Alternating?	Synchronous and Alternating	Synchronous and Alternating	Similar
Regulated Current or Regulated Voltage?	Regulated current (all channels)	Regulated current (all channels)	Similar
Software/Firmware/Microprocessor Control?	Yes	Yes	Similar
Automatic Shut Off?	Yes (timer)	Yes (timer)	Similar
Patient Override Control?	Yes	Yes	Similar
Biofeedback Feature	Yes	Yes	Similar
Indicator Display - On/Off Status?	Yes	Yes	Similar
Compliance with 21 CFR 898?	Yes, leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	Yes, leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	Similar
Weight	0.35lb	6lbs	Different
Dimensions in inches [W x H x D]	3.5”Wx5.9”Hx1.37”D	9.75”W x8.75”H x 12.75”D	Different

Output Specifications – Comparison with Predicate Device

VitalStim™ Square Symmetrical Biphasic Waveform Specification Matrix

Characteristic	New Device	Predicate Device	Similar/ Different
Waveform	Symmetrical Biphasic (DC Zero)	Symmetrical Biphasic (DC Zero)	Similar
Shape	Square	Square	Similar
Maximum Output Current (± 30%)			
500Ω	25mA	25mA	Similar
1000Ω	25mA	25mA	Similar

2000Ω	25mA	25mA	Similar
2500Ω	25mA	25mA	Similar
10000Ω	7mA	12mA	Different
Pulse Width	Fixed 300 µsec	Fixed 300µsec	Similar
Frequency Hz	Fixed 80 Hz	Fixed 80Hz	Similar
Ramp Time	2sec	2sec	Similar
For multiphasic waveforms only:	Yes	Yes	Similar
Symmetrical phases?	Yes	Yes	Similar
Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Fixed 300µsec	Fixed 300µsec	Similar
Net Charge [µC/pulse]	0 µC	0 µC	Similar
Stim + EMG Biofeedback	Yes	Yes	Similar

Output Specifications – Comparison with Predicate Device
VMS™ Square Symmetrical Biphasic Waveform Specification Matrix

Characteristic	New Device	Predicate Device	Similar/ Different
Waveform	Symmetrical Biphasic (DC Zero)	Symmetrical Biphasic (DC Zero)	Similar
Shape	Square	Square	Similar
Maximum Output Current (± 30%)			
500Ω	25mA	25mA	Similar
1000Ω	25mA	25mA	Similar
2000Ω	25mA	25mA	Similar
2500Ω	25mA	25mA	Similar
10000Ω	7mA	12mA	Different
Pulse Width	60-300 µsec	100 - 300µsec	Different
Frequency Hz	1 to 80 Hz	5 to 80 Hz	Different
Ramp Time	0-3 sec	2 sec	Different
For multiphasic waveforms only:	Yes	Yes	Similar
Symmetrical phases?	Yes	Yes	Similar
Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	60-300µsec	100 - 300µsec	Different
Stim + EMG Biofeedback	Yes	Yes	Similar

Although there are minor differences in the maximum output current, the physical dimensions, and the batteries used as a power source, the most significant difference between the two devices is the absence of HVPC™-Monophasic Pulsed waveform.

The intended use of the HVPC™-Monophasic Pulsed waveform of the VitalStim Experia device is the same as the VMS waveform offered in both the VitalStim Plus and the VitalStim

Experia devices. HVPC™-Monophasic Pulsed waveform is only an optional application of the same intended use. The same intended use can be achieved by the VMS waveform. Therefore, absence of HVPC™-Monophasic Pulsed waveform does not raise any question in regards to safety and effectiveness and is substantially equivalent.

Performance Testing:

Electrical Safety and Electromagnetic Compatibility: The VitalStim® Plus Electrotherapy System 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 60601-1-6 for usability
- IEC 60601-1-11 for home healthcare
- IEC 60601-2-10 for performance of nerve and muscle stimulators

FCC Testing: The VitalStim® Plus Electrotherapy System was tested to FCC requirements and found to comply with the requirements of the following regulation:

- FCC Part 15 Subpart B:2008 Class B
- FCC CFR Title 47 Part 15 Subpart C

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.

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

Conclusion:

Based on the performance testing and the supporting documentation, it can be concluded that the VitalStim® Plus Electrotherapy System is as safe and effective as, and substantially equivalent to, the predicate device.