DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 3, 2016

DJO, LLC
Rand Daoud
Regulatory Affairs Specialist III
1430 Decision St.
Vista, CA 92081

Re: K153704
Trade/Device Name: Strive™
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ, NUH, NYN
Dated: April 21, 2016
Received: April 22, 2016

Dear Rand Daoud:

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 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)*
K153704

Device Name

Strive™

Indications for Use *(Describe)*

Prescription Use:
The Strive™ TENS device is used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. It is also used as an adjunctive treatment for post-surgical and post-trauma acute pain.

As a TENS device, indications are for the following conditions:
- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

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 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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Section 5:

510(k) Summary

Section 5. 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 K153704.

Submitted by:	DJO, LLC 1430 Decision Street Vista, CA 92081
Contact Person:	Rand Daoud Regulatory Specialist III 760-734-3037
Date Summary Prepared:	December 23, 2015
Trade Name:	Strive™
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief (21 CFR 882.5890)
Product Code:	GZJ (primary code) NUH (primary code) NYN (subsequent code)
Regulatory Class:	Class II
Predicate Device:	EMPI Select (K061650) EMPI Phoenix (K124016) SmartRelief (K131159)

Device Description:

The Strive device is a handheld Transcutaneous Electrical Nerve Stimulation (TENS) unit which delivers electrical pulses transmitted by electrodes to cutaneous (surface) and afferent (deep) nerves of the body for pain management. The device provides simple user interface and programming, and is aimed to be used with lead wires and electrodes. Strive will be marketed as either Prescription (RX for U.S. Only) or Over-the-Counter (OTC), with each configuration having its own set of labeling, as appropriate.

The Strive device utilizes electrodes which are single patient use only. The device embeds a rechargeable battery that cannot be removed. The device is inoperable while the battery is charging.

Indications for Use:

Prescription Use:

The Strive device is used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. It is also used as an adjunctive treatment for post-surgical and post- trauma acute pain.

As a TENS device, indications are for the following conditions:
-Symptomatic relief and management of chronic, intractable pain
-Adjunctive treatment for post-surgical and post-trauma acute pain
-Relief of pain associated with arthritis

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 and management of chronic, intractable pain and relief of pain associated with arthritis.

Programs:

Strive provides two different TENS programs (P1 and P2) based on the same waveform: a balanced asymmetrical biphasic waveform that has nominally constant current in the positive phase and a second logarithmic waveform which decreases current in the negative phase. These programs are pre-installed in the Strive device and can be used interchangeably based on physician prescription (under RX use) and/or provided device program selection instructions (under OTC use).

The following is a description of programs P1 and P2:

SMP program (P1)
The SMP program combines two pain relief principals, High Frequency TENS and Low Frequency TENS. P1 delivers a group of pulses as a repeating 12-second cycle varies from low frequencies to high frequencies. Within each cycle, the rate and duration of the pulses vary as shown in Figure 11.2 below. The frequency varies from 5Hz to 122Hz and the pulse duration varies from 300μs (at low frequencies) to 70μs (at high frequencies).

The program is built to provide at the time high frequency TENS (during 9.5s of total period) and low frequency TENS (during 2.5s of total period). The pulse duration variation is done to avoid strong contraction during 12s cycle and thus increase usage comfort.

Frequency modulated TENS program (P2)
The modulated TENS program relies solely on the first principle of pain relief, High Frequency TENS, for the treatment of post-surgical or chronic pain.

This program has a frequency modulation range of 90 to 120pps, and a period of 4s cycle times, with a fixed pulse duration of 80μs.

Comparison to the Predicate Devices:

The indications for use for Strive are identical to those of the predicate devices, EMPI Select, EMPI Phoenix and SmartRelief.

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

The following tables summarize the similarities and differences between the technological characteristics of the devices.

Table 1a: Basic Device Characteristics – Comparison with Predicate Rx Devices

Characteristic	New Device	Predicate Device	Predicate Device	Same / Different
510(k) Number	K153704	K061650	K124016	NA
Device Name	Strive	EMPI Select	EMPI Phoenix	NA
Manufacturer	DJO, LLC.	DJO, LLC.	DJO, LLC.	NA
Indications for Use	-Symptomatic relief and management of chronic, intractable pain. -Adjunctive treatment for post-surgical and post-trauma acute pain. -Relief of pain associated with arthritis.	-Symptomatic relief and management of chronic, intractable pain. -Adjunctive treatment for post-surgical and post-trauma acute pain -Relief of pain associated with arthritis.	*As a TENS device, indications are for the following conditions*: -Symptomatic relief and management of chronic, intractable pain -Adjunctive treatment for post-surgical and post-trauma acute pain -Relief of pain associated with arthritis	Similar

Prescription/OTC	Prescription	Prescription	Prescription	Same
TENS Programs	SMP Mode (**SMP**) Frequency Modulation (**FM**)	Strength Duration (SD) Alternating Ramped Burst (ARB), SMP Mode (**SMP**) Modulation Amplitude (MA), Continuous (C), Cycled Burst (B), Modulation (M).	Frequency Modulated TENS (**FM**)	Similar SMP for Strive and Select are the same. FM for Strive and Phoenix are same.
Connection of device to electrodes	Lead wires	Lead wires	Leadwires and garment	Same
Power Source(s)	LiPo 250[mAh] (3.7[V]), not removable	Alkaline or Rechargeable (3 AAA)	2 AA LR06 Batteries, 1.5 V Alkaline or 1.2 V NiMh rechargeable	Different
- Method of line current isolation	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Same
- Patient Leakage Current	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Same
• Normal condition	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Same

• Single fault condition	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Same
Number of Output Modes	2(2xTENS)	7 (7xTENS)	4 (1xTENS, 2xNMES, 1xPulsed Current DC)	Different
Number of Output Channels	1, split	2	2	Similar
- Synchronous or Alternating?	NA	Program dependent	Synchronous but never two channels activated at the same time	Different
- Method of Channel Isolation	NA	Transformer	Each channel is the middle of an H Bridge. Except when it is activated, each channel is in high impedance state.	Different
Regulated Current or Regulated Voltage?	Regulated Current	Constant voltage pulse, constant current undershoot	Regulated Current	Different
Software/Firmware/ Microprocessor Control?	Yes, Microcontroller	Yes, Microprocessor	Yes.	Same
Automatic Overload Trip?	No	No	No	Same
Automatic No-Load Trip?	Yes	Yes	Yes	Same
Automatic Shut Off?	Yes	Yes	Yes	Same

Patient Override Control?	No	No	Yes (On/Off switch)	Different
Indicator Display - On/Off Status?	Yes (P1 & P2, Output Indicators)	Yes (LCD)	Yes	Same
- Low Battery?	No	Yes. Battery icon on LCD.	Yes	Different
- Voltage/Current Level?	Active/inactive output	Yes, numeric value on LCD	Yes	Different
Timer Range (minutes)	Unlimited	Unlimited	20 minutes (P1 and P2), 30 minutes (P4), Unlimited (P3)	Similar
Compliance with 21 CFR 898?	Yes	Yes	Yes	Same
Weight	0.99 oz	4.9 oz with batteries	170 g with batteries	Different
Dimensions [W x H x D]	49 mm x 64mm x 14 mm	109mm x 61mm 36 mm	67mm x 135mm x 30mm	Different

Table 1b: Basic Device Characteristics – Comparison with Predicate OTC Device

Characteristic	New Device	Predicate Device	Same / Different
510(k) Number	K153704	K131159	NA
Device Name	Strive	SmartRelief	NA
Manufacturer	DJO, LLC.	Chattem, Inc.	NA

Indications for Use	-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.	-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.	Same
Prescription/OTC	OTC	OTC	Same
TENS Programs	SMP Mode (**SMP**) Frequency Modulation (**FM**)	TENS (SMP)	Similar
Connection of device to electrodes	Lead wires	Snaps on the device	Different
Power Source(s)	LiPo 250[mAh] (3.7[V]), not removable	Lithium Battery Coin cell CR2032 3V	Different
- Method of line current isolation	N/A (battery operated device)	N/A (battery operated device)	Same
- Patient Leakage Current	N/A (battery operated device)	N/A (battery operated device)	Same
• Normal condition	N/A (battery operated device)	N/A (battery operated device)	Same
• Single fault condition	N/A (battery operated device)	N/A (battery operated device)	Same
Number of Output Modes	2(2xTENS)	1 (TENS)	Different
Number of Output Channels	1, split	1	Similar

- Synchronous or Alternating?	NA	NA	Same
- Method of Channel Isolation	NA	NA	Same
Regulated Current or Regulated Voltage?	Regulated Current	Regulated Current	Same
Software/Firmware/ Microprocessor Control?	Yes, Microcontroller	Yes, micro controller	Same
Automatic Overload Trip?	No	No	Same
Automatic No-Load Trip?	Yes	No	Different
Automatic Shut Off?	Yes	Yes	Same
Patient Override Control?	No	No	Same
Indicator Display - On/Off Status?	Yes (P1 & P2, Output Indicators)	Yes	Same
- Low Battery?	No	No	Same
Voltage/Current Level?	Active/inactive output	Active/inactive output	Same
Timer Range (minutes)	Unlimited	Yes (30min)	Different

Compliance with 21 CFR 898?	Yes	Yes	Same
Weight	0.99 oz	20g (0.7oz)	Different
Dimensions [W x H x D]	49 mm x 64mm x 14 mm	64x38x13[mm] (2.5x1.5x0.5[’’])	Different

Table 2: Output Specifications – Comparison with EMPI Select Predicate Device

Characteristic	**New Device**	**Predicate Device (EMPI Select)**	**Same/ Different**
Output mode / Program	P1 (SMP)	SMP	Same
Waveform	Balanced, Asymmetrical Biphasic	Balanced, Asymmetrical Biphasic	Same
Shape	Square positive pulse, current controlled Logarithmic negative pulse, decrease current.	AC, constant current undershoot; constant voltage pulse	Different
Maximum Output Voltage (± 10%)	110[V] peak on 10[kΩ] 110[V] peak on 2[kΩ] 60[V] peak on 1[kΩ] 30[V] peak on 500[Ω]	0[V] (open lead) peak on 10[kΩ] 40[V] peak on 2[kΩ] 30[V] peak on 1[kΩ] 30[V] peak on 500[Ω]	Different
Maximum Output Current (± 10%)	11[mA] peak on 10[kΩ] 55[mA] peak on 2[kΩ] 60[mA] peak on 1[kΩ] 60[mA] peak on 500[Ω] Max rms current 6.28[mA]rms (divided by 2 per output when split)	0[mA] (open lead) peak on 10[kΩ] 20[mA] peak on 2[kΩ] 30[mA] peak on 1[kΩ] 60[mA] peak on 500[Ω] Max rms current 11[mA]rms	Same
Pulse Width	70 to 300[μs] (measured at 50% of positive pulse)	0-400 μs at 50% of peak amplitude	Similar

Frequency	5 to 122[Hz]	2, 5-150 Hz, 5Hz increments	Similar
For multiphasic waveforms only: - Symmetrical phases? - Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Biphasic: - Asymmetrical - 70 to 300[µs] for positive pulse, logarithmic negative pulse, decrease current.	Biphasic: - Asymmetrical - 0 to 400[µs] for positive pulse, constant current undershoot	Same
Net Charge [µC/pulse]	18[uC] on 1[kΩ]	12[uC] / output on 1 [kΩ] load (24[uC] CH1 & 2 together)	Different
Maximum Phase Charge [µC] Maximum Current (RMS) Density [mA/cm^2]	0[uC] on 1[kΩ] 0.31[mA/cm^2] (over 1[s] period)	0[uC] / output on 1 [kΩ] load 11 [mA]	Same Same
Maximum Power Density [mW/cm^2]	4.92[mW/cm^2] (split on 2x1[kΩ] in //)	44[mW/cm^2] per output, on 1[kΩ]	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)]	NA, no burst mode	a) 29[pulses/burst] b) 0.39[burst/s] c) 1.9[s]	Different
ON Time (seconds)	Once started, the output is active until user manually stops the unit	Depends on the selected program	Different
OFF Time (seconds)	NA, no OFF time	Depends on the selected program	Different
Additional Features (if applicable)	NA, no additional feature	NA, no additional feature	Same

Table 3: Output Specifications – Comparison with EMPI Phoenix Predicate Device

Characteristic	New Device	Predicate Device (EMPI Phoenix)	Similar/ Different
Output mode / Program	P2 (Frequency Modulated TENS)	Frequency Modulated TENS (P3)	Same
Waveform	Balanced, Asymmetrical Biphasic	Symmetrical Biphasic	Similar
Shape	Square positive pulse, current controlled Logarithmic negative pulse, decrease current.	Rectangular	Different
Maximum Output Voltage (± 10%)	110[V] peak on 10[kΩ] 110[V] peak on 2[kΩ] 60[V] peak on 1[kΩ] 30[V] peak on 500[Ω]	150[V] peak on 10[kΩ] 150[V] peak on 2[kΩ] 100[V] peak on 1[kΩ] 50[V] peak on 500[Ω]	Different
Maximum Output Current (± 10%)	11[mA] peak on 10[kΩ] 55[mA] peak on 2[kΩ] 60[mA] peak on 1[kΩ] 60[mA] peak on 500[Ω] Max rms current 6.28[mA]rms (divided by 2 per output when split)	15[mA] peak on 10[kΩ] 75[mA] peak on 2[kΩ] 100[mA] peak on 1[kΩ] 100[mA] peak on 500[Ω] Max rms current 21.2[mA]rms	Different
Pulse Width	80[μs] (measured at 50% of positive pulse)	80μs	Same
Frequency	90 to 120[Hz]	90-120 Hz	Same
For multiphasic waveforms only: - Symmetrical phases? - Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Biphasic: - Asymmetrical - 70 to 300[μs] for positive pulse, logarithmic negative pulse, decrease current.	NA	Different
Net Charge [μC/pulse]	18[μC] @ 500[Ω]	30 μC @ 500Ω	Different

Maximum Phase Charge [μC]	0[μC] on 1[kΩ]	0[μC] / output on 1 [kΩ] load	Same
Maximum Current (RMS) Density [mA/cm2]	0.33[mA/cm^2] (over 1[s] period)	1.44 mA/ cm^2@ 500Ω	Different
Maximum Power Density [mW/cm^2]	5.53[mW/cm^2] @ 500[Ω]	0.0111W/cm^2 @ 500Ω	Different
Burst Mode (i.e. pulse trains) e) Pulses per burst f) Bursts per second g) Burst duration (seconds) h) Duty Cycle [Line (b) x Line (c)]	NA, no burst mode	NA	Same
ON Time (seconds)	Once started, the output is active until user manually stops the unit	Constant (without handswitch)	Different
OFF Time (seconds)	NA, no OFF time	0 (without handswitch)	Different
Additional Features (if applicable)	NA, no additional feature	NA	Same

Table 4: Output Specifications – Comparison with Chattem SmartRelief Predicate Device

Characteristic	**New Device**	**Predicate Device (SmartRelief)**	**Similar/ Different**
Output mode / Program	P1 (SMP)	TENS (SMP)	Similar
Waveform	Balanced, Asymmetrical Biphasic	Balanced, Asymmetrical Biphasic	Similar
Shape	Square positive pulse, current controlled Logarithmic negative pulse, decrease current.	Square positive pulse, current controlled Logarithmic negative pulse, decrease current.	Similar

Maximum Output Voltage (± 10%)	110[V] peak on 10[kΩ] 110[V] peak on 2[kΩ] 60[V] peak on 1[kΩ] 30[V] peak on 500[Ω]	70[V] peak on 10[kΩ] 70[V] peak on 2[kΩ] 60[V] peak on 1[kΩ] 30[V] peak on 500[Ω]	Different
Maximum Output Current (± 10%)	11[mA] peak on 10[kΩ] 55[mA] peak on 2[kΩ] 60[mA] peak on 1[kΩ] 60[mA] peak on 500[Ω] Max rms current 6.28[mA]rms (divided by 2 per output when split)	7[mA] peak on 10[kΩ] 35[mA] peak on 2[kΩ] 60[mA] peak on 1[kΩ] 60[mA] peak on 500[Ω] Max rms current 3[mA]rms	Similar
Pulse Width	70 to 300[μs] (measured at 50% of positive pulse)	30-220 μs at 50% of peak amplitude	Similar
Frequency	5 to 122[Hz]	max 100[Hz]	Similar
For multiphasic waveforms only: - Symmetrical phases? - Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Biphasic: - Asymmetrical - 70 to 300[μs] for positive pulse, logarithmic negative pulse, decrease current.	Biphasic: - Asymmetrical 30 to 220[μs] for positive pulse, constant current undershoot	Similar
Net Charge [μC/pulse]	18[μC] @ 1[kΩ]	13.2[uC]	Different
Maximum Phase Charge [μC]	0[μC] on 1[kΩ]	0[uC]	Similar
Maximum Current (RMS) Density [mA/cm2]	0.31[mA/cm^2] (over 1[s] period)	0.1[mA/cm^2] (2.06[mA]/20[cm^2])	Similar
Maximum Power Density [mW/cm^2]	4.92[mW/cm^2] (split on 2x1[kΩ] in //)	1.5[mW/cm^2] (60mA*70V*2*40us * 90Hz) / 4.5^2cm^2	Different

Burst Mode (i.e. pulse trains) i) Pulses per burst j) Bursts per second k) Burst duration (seconds) l) Duty Cycle [Line (b) x Line (c)]	NA, no burst mode	NA, no burst mode	Same
ON Time (seconds)	Once started, the output is active until user manually stops the unit	30[min]	Different
OFF Time (seconds)	NA, no OFF time	NA, no OFF time	Same
Additional Features (if applicable)	NA, no additional feature	NA, no additional feature	Same

Although there are minor differences observed between the predicate devices and Strive, seen in the tables above, there are no differences in which raise any new questions of safety or effectiveness.

Performance Testing:

Electrical Safety and Electromagnetic Compatibility: Strive testing comprises of 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.

Usability/Human Factors Testing: Usability/Human Factors testing was performed in accordance to standard IEC 60601-1-6, 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.

Coexistence Testing: The performance of Strive was evaluated in an environment with other devices (Bluetooth, Wi-Fi, Microwave Oven), as well as in an environment with clinical devices which intentionally and unintentionally emit RF frequencies. The device met all specified requirements.

Conclusion:

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