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

August 4, 2017

Hi-Dow International, Inc.
% Schevon Salmon
Associate Attorney
Benjamin L. England & Associates, LLC
810 Landmark Drive, Suite 126
Glen Burnie, Maryland 21061

Re: K163393
Trade/Device Name: Hi-Dow Wireless TENS/EMS (Model HD-5N)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: July 11, 2017
Received: July 13, 2017

Dear Schevon Salmon:

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

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)*
K163393

Device Name
Hi-Dow Wireless TENS/EMS System (Model HD-5N)

Indications for Use *(Describe)*
TENS:
To be used for the temporary relief of pain associated with sore or aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

EMS:
It is intended for muscle conditioning, used for stimulating muscles including abdomen muscles in order to improve or facilitate muscle performance.

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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7. 510(k) Summary

Date of Summary Preparation: 8/4/2017

1. Submitter

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Tel: 314 569 2888
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E-mail: echen@hidow.com
Contact: Mr. Eric Chen

2. Name of the Device

Proprietary Name:	Hi-Dow Wireless TENS/EMS System, Model HD-5N
Common Name:	1. Transcutaneous Electrical Nerve Stimulator for pain relief: TENS 2. Powered Muscle Stimulator
Classification:	1. Stimulator, Nerve, Transcutaneous, Over-The-Counter 2. Stimulator, Muscle, Powered, Over-the-Counter
Classification Regulation:	1. 21 CFR 882.5890 2. 21 CFR 890.5850
Product Code:	1. NUH 2. NGX
Classification Panel:	1. Neurology 2. Physical Medicine
Device Classification:	Class 2
Contraindications:	Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

3. The Predicate Device

K102598, Hi-Dow Model JQ-5C
Powered Muscle Stimulator (21 CFR 890.5850)
Transcutaneous Electrical Nerve Stimulator for pain relief (21 CFR 882.5890)
This predicate has not been subject to a design-related recall.

4. Secondary Predicate

K130723, FDES106(ED406) Mini TENS&EMS Device
Powered Muscle Stimulator (21 CFR 890.5850)
Transcutaneous Electrical Nerve stimulator for pain relief (21 CFR 82.5890)

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5. Reference Device

K120398, WiTouch™ Pro, (Transcutaneous electrical nerve stimulator for pain relief) 21CFR 882.5890. This device is included to provide an example of a cleared radiofrequency controlled device in the TENS/PMS regulatory classification; it is not included for its specific intended use or product code. The Subject Device has very similar technological specifications and is in the same regulatory category.

6. Device Description

The Hi-Dow Wireless TENS/EMS System is a battery operated wireless pulse generator that uses radiofrequency signals sent from a wireless remote control unit to wireless receivers attached to the electrodes(s), which are attached to the skin at the area to be treated. The wireless remote controls the intensity and mode functions of the receiver. When used in TENS Modes, the electrical impulses generated by the receivers stimulate the nerves that are causing pain resulting in gentle electrical sensations instead of pain. When used in EMS modes, the electrical impulses generated by the receivers produce muscle contractions, these contractions help to condition and improve the muscles.

The Hi-Dow Wireless TENS/EMS System is a double-channel and 4 modes muscle stimulation system that helps to relieve minor muscular aches and pains.
The output of both channels can be adjusted individually for intensity in 20 levels and the treatment time is 45 minutes.

The device is powered by rechargeable Lithium Batteries which are permanently built into the main unit and can be recharged with the charging unit supplied with the device.

The Device consists of an electronic stimulatory module which generates the required stimulation signals, 3 sets of electrode pads and a plug-in charging unit.

The electrodes are designed for single-patient/multiple application use. Because of the adhesive nature of the biocompatible conductive hydro gel, no securing materials are required to secure the device to the patient's skin. The electrodes snap onto the receiver.

7. Intended Use of Device

TENS
The Hi-Dow Wireless TENS/EMS System, Model HD-5N is intended to be used for temporary relief of pain associated with sore or aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

EMS
Intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

8. Summary of Substantial Equivalence

The Hi-Dow Wireless TENS/EMS System, Model HD-5N and HI-Dow, Model JQ-5C (K102598) devices are very similar. They deliver essentially the same electrical energy transdermally using electrodes and gel. They differ in how the control unit interacts with the

7. 510(k) Summary

electrodes. In Model JQ-5C, the control and the power delivery functions are housed in the same unit. Electrodes, attached to the patient, are connected directly to the control/power unit. The wireless device (Model HD-5N) separates the control aspect from the electrical power delivery unit. The Hi-Dow Wireless TENS/EMS system separates the control aspects from the electrical power delvery unit. The control unit sends radiofrequency signals to the receiving power delivery unit which generates impulses according to the corresponding mode of operation and level of treatment.

The technological characteristics of the Hi-Dow Wireless TENS/EMS System and secondary predicate, FDES106(ED406) Mini TENS&EMS Device, are very similar. They both deliver electrical energy transdermally using electrodes. They differ in how the control unit interacts with the electrodes and the performance data. In FDES106(ED406), the control and power delivery are housed in the same unit and electrodes are connected directed to the control/power unit. The devices also use AA batteries.

Table: The table below provides analysis of the similarities and difference between HD-5N, the predicate ((K102598 JQ-5C) and the secondary predicate device (K130723).

9. Comparison of Technological Characteristics with the Predicate Devices

14. Substantial Equivalence Discussion

Elements of Comparison	**Subject device**	**Predicate Device**	**Secondary Predicate Device**
510(k) Number	K163393	K102598	K130723
Device Name and Model	Powered Muscle Stimulator and Transcutaneous electrical nerve stimulator for pain relief HD-5N	JQ-5C	FDES106(ED406) Mini TENS&EMS Device
Manufacturer	Hi-Dow Electron Technology(Hefei) Inc., Ltd.	Hefei Jianqiao Sci-tech Development Co., Ltd	Famidoc Technology Co., Ltd
Intended Use & Indications for Use	TENS To be used for the temporary relief of pain associated with sore or aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. EMS: Intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	To be used for the temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	For program N, B and H of TENS mode To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household work activities. For program El and E2 of EMS mode Used to stimulate healthy muscles in order to improve and facilitate muscle performance.
Basic Unit Characteristics			
Device Power Source(s)	DC 3.7V Lithium Battery	DC 3.7 V Lithium Battery	Battery powered, d.c. 3.0V, 2 X AAA batteries
-Method of Line Current Isolation	Type BF Applied Part	Type BF Applied Part	Type BF Applied Part

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Patient Leakage Current	NC	DC:<10μA AC:<100 μA	DC:<10μA AC: <100 μA	0.9μA
	SFC	DC:<50μA AC:<500 μA	DC:<50μA AC: <500 μA	0.8μA
Number of Output Channels		2	2	1
Number of Output Modes		4	6	5
Synchronous or Alternating?		2 Channel Asynchronous	2 Channel Synchronous	Alternating
Method of Channel Isolation		Two separate devices, and use independent power supply system.	Parallel	By Electrical Circuit and Software
Regulated Current or Regulated Voltage?		Regulated Voltage	Regulated Voltage	Regulated Voltage
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes
Automatic Overload Trip?		No	No	Yes
Automatic No-Load Trip?		No	No	Yes
Automatic Shut Off		Yes	Yes	Yes
User Override Control?		Yes	Yes	Yes
Indicator Display	On/Off Status?	Yes	Yes	Yes
	Low Battery?	Yes	Yes	Yes
	Voltage/Current Level?	No	No	No
Timer Range		45mins	10 ~ 60mins	30 mins
Compliance with 21 CFR 898?		Yes	Yes	Yes
Weight (lbs., oz,)		Remote: 2.2 oz. Receiver: 0.85oz.	1.5 oz.	.093 oz.
Dimensions (in.) [W x H x D]		Remote: 4.25”(W) x 2.1” (H) x 0.6” (D) Receiver:Φ2.25” (Diameter) x 0.47”(D)	3.15”(W) x 1.65” (H) x 0.55”(D)	2.5”x1.77”x0.36”

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Electrode shape(square, round, rectangular, oval) and size(L*W(cm)or area cm^2)		Oval electrode pad(gel), 4.5*3cm, 12cm^2; Rectangular electrode pad(gel), 9*4cm, 36cm^2; Rectangular electrode pad(gel), 9*6cm, 54cm^2;	Oval electrode pad(gel), 9cm^2;	N/A
Housing Material and Construction		ABS	ABS and metal	Plastic (ABS) Enclosure
Output Specifications				
Waveform (e.g., pulsed monophasic, biphasic)		Pulsed Biphasic	Pulsed Biphasic	Pulsed Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular	Square
For multiphasic waveforms only:	Symmetrical phases?	YES	YES	Yes
	Step-i and Step-3 Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	TENS & EMS : 100μS	100μS	-
	Step-2 Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	TENS & EMS : 100μS	100μS	-
Frequency (Hz)		(TENS) MODE 3: 1.28 (TENS) MODE 4: 1~59.8 (EMS) MODE 1: 52.3 (EMS) MODE 2: 5.8	1~68	TENS: 2 ~ 80 EMS: 2 ~ 50

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phase Duration(include units) (S)		(TENS) MODE 3: Continuous (TENS) MODE 4: 92.5 (EMS) MODE 1: 4.6 (EMS) MODE 2: 4.8	Continuous / 4.5~93	TENS: 200 ~ 350μS EMS: 250μS
Maximum output Voltage ,(V_{peak},specify units v)		(TENS) MODE 3: 48.5V@500Ω (TENS) MODE 4: 41.1V@500Ω (EMS) MODE 1: 37.9V@500Ω (EMS) MODE 2: 46.8V@500Ω	62.4V@500Ω	TENS: 30.4V@500Ω EMS: 28V@500Ω
Maximum output Current, (I_{peak}, specify units mA)		(TENS) MODE 3: 97mA@500Ω (TENS) MODE 4: 82.2mA@500Ω (EMS) MODE 1: 75.8mA@500Ω (EMS) MODE 2: 93.6mA@500Ω	124.8mA@500Ω	TENS: 60.8mA@500Ω EMS: 56mA@500Ω
Net Charge, (μC per pulse)		(TENS) MODE 3: 9.7μC@500Ω (TENS) MODE 4: 8.22μC@500Ω (EMS) MODE 1: 7.5μC@500Ω (EMS) MODE 2: 9.36μC@500Ω	0μC@500Ω	TENS: 15.2μC@500Ω EMS: 14μC@500Ω
Maximum phase Charge, (μC)		(TENS) MODE 3: 38.8μC@500Ω (TENS) MODE 4: 32.88μC@500Ω (EMS) MODE 1: 15μC@500Ω (EMS) MODE 2: 37.44μC@500Ω	49.92μC@500Ω	TENS:15.2μC@500Ω EMS: 14μC@500Ω
Maximum Current Density, (mA/cm²)		(TENS) MODE 3: 8.08mA/cm²@500Ω (TENS) MODE 4: 6.85mA/cm²@500Ω (EMS) MODE 1: 6.31mA/cm²@500Ω (EMS) MODE 2: 7.8mA/cm²@500Ω	13.86mA@500Ω	TENS: 4.1mA/cm²@500Ω EMS: 3.77mA/cm²@500Ω
Maximum Average Current(mA).		(TENS) MODE 3: 0.0124mA@500Ω (TENS) MODE 4: 0.492mA@500Ω (EMS) MODE 1: 0.393mA@500Ω (EMS) MODE 2: 0.054mA@500Ω	0.761mA@500Ω	TENS: 0.51mA@500Ω EMS: 0.41mA@500Ω
Maximum Average Power Density, (mW/CM²), (using smallest electrode conductive surface area)		(TENS) MODE 3: 0.05W/cm²@ 500Ω (TENS) MODE 4: 1.68W/cm²@ 500Ω (EMS) MODE 1: 1.25W/cm²@ 500Ω (EMS) MODE 2: 0.21W/cm²@ 500Ω	5.27 mW/cm2@ 500Ω	TENS: 2mW/cm²@500Ω EMS: 1.2mW/CM²@500Ω
Burst Mode(i.e., pulse trains)	Pulses per burst	Continuous / complex; 41~181	Continuous / 38.5~510	TENS: 7
	Bursts per second	Complex / 0.208~0.217	0.086~0.78	TENS: 2
	Burst duration(seconds)	Continuous / 4.6~92.5	Continuous / 4.5~93	TENS: .02
	Duty Cycle [Line(b) x Line(c)]	0.0128% ~0.589%	0.0128% ~0.61%	TENS: 1.4

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	ON Time(seconds)	0.1	0.1	-
	OFF Time(seconds)	0.1	0.1	-
Remote communication mode?		RF: 2.4GHz transceiver	N/A	N/A
Wireless		FCC Part 15 Conducted Emissions FCC Part 15 Radiated Emissions Remote Control: FCC ID:2ACD4HD-5N-TX Device: FCC ID:2ACD4HD-5N-RX	N/A	N/A
Additional Features				
Environment for operating		Temperature：5℃ to 40℃(41°F~104°F) Humidity(non-condensing) ：30%-75%, Atmospheric pressure：700 to 1060Hpa	Temperature: 10℃~40℃ (50°F~104°F) Humidity(non-condensing) ：≤80% Atmospheric pressure: 800~1050Hpa	Temperature：5℃ to 40℃(41°F~104°F) Humidity(non-condensing) ：30%-85%,
Environment for storage		Temperature: -10℃to55℃ (14°F~131°F) Humidity(non-condensing) ：10%-90% Atmospheric pressure：700 to 1060Hpa	Temperature: -20℃~60℃ (-4°F~140°F) Humidity(non-condensing) ：10~95%	Temperature: -10℃to50℃ (14°F~122°F) Humidity(non-condensing) ：10%-90% (non-condensing)
Standards				
Biocompatibility		All user directly contacting materials are compliance with ISO10993-1:2009/C1：2010, ISO10993-5:2009, ISO10993-10:2010.	EN ISO 10993-1:2009	Compliant with requirements of ISO 10993-5 and ISO 10993-10 standards
Electrical Safety		IEC 60601-1:2005 (Third Edition) + Corr. 1:2006 + Corr. 2:2007 + A1:2012 (or IEC 60601-1:2012 reprint); IEC 60601-2-10:2012; also complies with ANSI/AAMI ES60601-1:2005 + A1:2012, C1: 2009 and A2: 2010 EN 60601-1: 2006 EN 60601-2-10: 2000 + A1: 2001	EN 60601-1: 2006 EN 60601-2-10: 2000 + A1: 2001	Compliant with requirements IEC 60601-1, IEC 60601-2-10, IEC 60601-1-1-2
EMC		IEC 60601-1-2:2007, IEC 60601-1-11:2010 Clause 12, IEC 60601-2-10:2012 Clause 201.17&202;	EN60601-1, EN60601-1-2, EN ISO 14971:2009, EN 60601-2-10:2000 + A1:2001	Compliant with requirements IEC 60601-1-2, IEC 60601-2-10.

10. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the electrodes and the gel used with these devices was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the flowing tests:

ISO10993-1: 2009, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
ISO10993-5:2009, Biological Evaluation of Medical Devices- Part 5: Tests for In Vitro Cytotoxicity
ISO10993-10:2010, Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization

Electrical safety and electromagnetic compatibility (EMC) and Other Standards

The following tests were performed on the Hi-Dow Wireless TENS/EMS System, Model HD-5N device in accordance with the requirements of the design control regulations and established quality assurance procedures.

IEC60601-1:2005, Medical electrical equipment-Part 1: General requirements for basic safety, and essential performance. Also complies with ANSI/AAMI ES60601-1:2005 + A1:2012, C1: 2009 and A2: 2010, Medical electrical equipment-Part 1: General requirements for basic safety, and essential performance.
IEC60601-1-2:2007,EN60601-1-2:2007,Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility-Requirements and tests.
IEC60601-2-10:2012/EN60601-2-10:2015 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulator
IEC 60601-1-11: 2010/EN 60601-1-11: 2010; 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
FCC Part 15 "Conducted Emissions"
FCC Part 15 "Radiated Emissions"

Software Verification and validation Testing

Software verification and validation testing were conducted and documents were provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could result in injury to

the patient or operator.

11. Conclusion

Based on the electrical characteristics tested under IEC 60601, the Hi-Dow Wireless Device performs the same as the cleared devices, the Hi-Dow Model JQ-5C and FDES106(ED406) Mini TENS&EMS Device. This supports the conclusion that it is as safe and as effective as the cleared devices for the stated indications.

---END OF 510(K) SUMMARY---