HEALTHCARE INNOVATIONS, LLC

K131956

APR 2 4 2014

Section 005 – 510(k) Summary

Applicant or Sponsor Information

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Establishment Registration:	TBD
Date of Submission:	23 June, 2013

Submission Correspondent (Preparer's) Information

Name:	Shepard G. Bentley, RAC
	President, Bentley Biomedical Consulting, LLC
	Consultant to Healthcare Innovations, LLC
Address:	28241 Crown Valley Parkway
	Suite 510(k)
	Laguna Niguel, CA 92677

Device Information

Device Common Name:	Transcutaneous electrical nerve stimulator for pain relief intended for over the counter use
Device Trade Name:	Quick Relax Pro
Device Classification Name:	Stimulator, nerve, transcutaneous, over-the –counter

Device Class:	Class II
Product Code:	NUH
CFR Reference:	882.5890
Predicate Device	K121757 HealthmateForever®

Design and Use of the Device

Hand held, 1.5 volt AA battery powered, single mode, single function device with ten "settings" that are controlled by means of rotating a marked disk that increases the microcurrent when rotated clockwise and decreases the microcurrent when rotated counterclockwise, directly through the device integrated electrode into the indicated region of the body. The purpose of the Quick Relax Pro is to provide a temporary relief of minor muscle pain within the indicated region of the body.

Technological Characteristics Comparison

Technical Characteristics	Quick Relax Pro	HealthmateForever® Pro-8AB
Intended Use	To be used for 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	To be used for 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
Battery Powered	1.5V DC	3.7V DC
Method of Line Current Isolation	Type BF	Type BF
Number of Output Modes	1	8
Waveform	Asymetrical Biphasic	Asymetrical Biphasic
Software	No	Yes
Functions	Single	Multiple

Parameter		Subject Device	Predicate Device
510(k) Number		K131956	K121757
Device Name and Model		Quick Relax Pro	HealthmateForever
Manufacturer		Healthcare Innovations, LLC	Healthmate International, LLC
Power Source(s)		Battery, single AA dry cell	Battery, single dry cell
-Method of Line Current Isolation		N/A	N/A
-Patient Leakage Current		N/A	N/A
-Normal Condition (μC)		N/A	N/A
-Single Fault Condition (μC)		N/A	N/A
Average DC current through electrodes when device is on but no pulses are being applied (μC)		N/A (pulses always applied when on)	N/A (pulses always applied when on)
Number of Output Modes		1	2
Number of Output Channels	Synchronous or Alternating?	N/A	N/A
	Method of Channel Isolation	N/A	N/A
Regulated Current or Regulated Voltage?		N/A	N/A
Software/Firmware/Microprocessor Control?		No	Yes
Automatic Overload Trip?		No	No
Automatic No-Load Trip?		No	No
Automatic Shut Off?		No	No
User Override Control?		No	Yes
Indicator Display:	On/Off Status?	Yes	Yes
	Low Battery?	No	Yes
	Voltage/Current Level?	Yes	Yes
Timer Range (minutes)		N/A	Yes
Compliance with Voluntary Standards?		Yes	Yes
Compliance with 21 CFR 898?		N/A	Presumed
Weight (lbs., oz.)		4.5 oz	3.9 oz
Dimensions (in) [W x H x D]		8.75" x 2" x 1.75"	3.75" x 2" x .5"
Housing Materials and Construction		Flame ret. ABS, stainless steel	Metal, LCD

Parameter		Subject Device	Predicate Device
Mode or Program Name		Output	Pro-8AB
Waveform (e.g., pulsed monophasic, biphasic)		Pulsed biphasic (asymmetrical unbalanced)	Pulsed biphasic (asymmetrical unbalanced)
Shape (e.g., rectified, spike, rectified sinusoidal)		Rectified sinusoidal (with undershoot)	Rectangular with taper
Maximum Output Voltage (volts) (+/-5%)		58.4v @ 500Ω 220v @ 2kΩ 995v @ 10kΩ applies measure prior to EnCadis' clarification – revised calculation is approx 300v @ 10kΩ	70v @ 500Ω 90v @ 2kΩ 100v @10kΩ
Maximum Output Current (mA) (+/- 5%)		117 mA @ 500Ω 110 mA @ 2kΩ 100 mA @ 10kΩ	140 mA @ 500Ω 45 mA @ 2kΩ 10 mA @ 10kΩ
Duration of primary (depolarizing) phase (µSec)		N/A	unknown
Pulse Duration (µSec)		11 µSec	10 mSec
Frequency (Hz)		30 Hz (max amplitude)	100 Hz
For multiphasic waveforms only:	Symmetrical phases?	No	No
	Phase Duration	Positive Phase: 11 µSec Negative Phase: 2 µSec (@ min amplitude, 500Ω load) 25 µSec (@ max amplitude, 10kΩ load)	Various, all are longer than Quick Relax Pro
Net Charge (microCoulombs (µC) per pulse)		0.78 µC *	Various, higher
Maximum Phase Charge (µC)		0.82 µC *	15.66 µC
Maximum Current Density (mA/cm2, r.m.s.)		3.37 mA/cm2 r.m.s.	7.2 mA/cm2 @500Ω

Parameter		Subject Device	Predicate Device
Maximum Average Current (average absolute value) mA		0.220 mA	Not measured
Maximum Average Power Density (W/cm2)		803 µW/cm2	Not measured
Burst Mode	(a) Pulses per burst	N/A	Various
	(b) Bursts per second	N/A	Various
	(c) Burst duration	N/A	Various
	(d) Duty Cycle: Line b x Line c	N/A	Various
ON Time (Sec)		N/A	1,200 default
OFF Time (Sec)		N/A	N/A
Additional Features		N/A	Unknown

Summary of Technological Characteristics Comparison

The foregoing comparison of the technological characteristics of the subject and predicate devices confirms that the devices are substantially equivalent with respect to intended uses, method of powering, physical descriptions, method of isolation and waveforms.

The differences regarding battery power, material descriptions, number of output modes, presence of software and overall numbers of functions confer an added degree of safety to the subject device.

Therefore, the subject device is at least as safe if not safer than the predicate device, and substantially equivalent with regard to the relevant comparators of the devices.

Summary of Non-Clinical Testing

The Quick Relax Pro has undergone biocompatibility testing of its tissue-contacting electrode in compliance with ISO 10993-5, ISO 10993-10 and ISO 10993-12. In addition, the Quick Relax Pro has undergone Product Safety testing in compliance to IEC 60601-1 and Electromagnetic Compatibility testing in compliance to IEC 60601-1-2. The results of each of the foregoing sets of test requirements were satisfactory, and serve to demonstrate the safety and effectiveness of the Quick Relax Pro.

The product safety, electromagnetic compatibility and biocompatibility test results provide assurance that the subject device performs as well or better than the predicate device.

The introduction of the Quick Relax Pro into interstate commerce does not raise any new issues of safety or effectiveness.

END OF 510(K) SUMMARY

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

April 24, 2014

Healthcare Innovations, LLC
c/o Shepard G. Bentley, RAC
Bentley Biomedical Consulting, LLC
28241 Crown Valley Parkway, Suite 510(k)
Laguna Niguel, CA 92677

Re: K131956
Trade/Device Name: Quick Relax Pro
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: March 4, 2014
Received: March 25, 2014

Dear Mr. Bentley:

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,

Carlos L. Peña -S

Carlos L. Peña, Ph.D., M.S.
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 on last page.

510(k) Number *(if known)*
K131956

Device Name
Quick Relax Pro

Indications for Use *(Describe)*
To be used for 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos D Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."