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 12, 2016

Counter Scientific Development (gz) Ltd
% Guenter Ginsberg
President
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, Florida 34135

Re: K150277
Trade/Device Name: Pain Therapy System, Model PTS-II
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH, NYN, NGX, GZJ
Dated: January 8, 2016
Received: January 11, 2016

Dear Guenter Ginsberg:

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)*
K150277

Device Name

Pain Therapy System, Model PTS-II

Indications for Use *(Describe)*

To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back due to strain from exercise or normal household work activities (Choose Mode A, B, or C)

To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (Arms) due to strain from exercise or normal household work activities (Choose Mode A, B or C)

To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (Legs) due to strain from exercise or normal household work activities (Choose Mode A, B or C)

To be used for symptomatic relief and management of chronic, intractable pain and relief of pain associated with Arthritis (Choose Mode A)

To stimulate healthy muscles in order to improve and facilitate muscle performance (Choose Mode B)

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

Date of Summary Prepared: 02/11/2016

1. Submitter's Name: Counter Scientific Development (GZ) Ltd
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2. Proposed New Device:

Trade Name: Pain Therapy System, Model PTS-II
Classification Name: TENS/EMS Device
Regulation Number: 882.5890 & 882.5850
Product Code: NUH, NGX, NYN, GZJ Device Class: II

3. Predicate (cleared) Device:

OTC TENS, Model T1040 aka Aurawave
510(k) Number: K124055
Manufacturer: Endurance Therapeutics

4. Description of Proposed Device:

The Pain Therapy System, Model PTS-II is a selectable dual channel TENS and EMS device operated by DC 3.0V (AAA*2 batteries). It is made up of one main unit, two electrode cables, and two pairs of electrode pads.

There are 3 selectable, pre-programmed output waveforms (modes) to choose from. The two channels share one knob to adjust, the intensity are adjustable from 0 to 5. Running time can be selected among 10, 20 or 40min and recycled. There is a dial with on/off on the side that enables the device to be turned on or off, and it can be used to adjust the output intensity level, turn clockwise to increase intensity and turn anticlockwise to decrease the intensity. In the front of the device, there are 2 buttons and 6 indicator lights, in which one button is the mode selection button, and the other is for time selection. There are three modes A, B, C, respectively indicated by three indicator lights, which are on the right of the mode selection button. The device has 3 timing levels, namely 10, 20, 40 min, and indicated by three indicator lights, which are on the right of the timing selection button.

The device has been tested to and meets the requirements of the following recognized consensus standards:

ANSI/AAMI ES60601-1:2005+Corr.1(2006)+Corr.2(2007) general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-06 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

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 disturbances - requirements and tests. (General II (ES/EMC))

5. Indication for Use:

This Pain Therapy System, Model PTS-II is:
To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back due to strain from exercise or normal household work activities (Choose Mode A, B, or C)

To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (Arms) due to strain from exercise or normal household work activities (Choose Mode A, B or C)

To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (Legs) due to strain from exercise or normal household work activities (Choose Mode A, B or C)

To be used for symptomatic relief and management of chronic, intractable pain and relief of pain associated with Arthritis (Choose Mode A)

To stimulate healthy muscles in order to improve and facilitate muscle performance (Choose ModeB)

6. Environment of Use:

Clinics, Hospitals and home environments

7. 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 electrical shock, burns, electrical interference, or death.

Do not use this device together with a life-supporting medical electronic device such as an artificial heart or lung.

Do not use this device together with a body-worn medical electronic device such as an ECG.

8. Technological Characteristics Compared to the Predicate Device

510(k) Number	**K150277**	**K124055**
Device Name and Model	PAIN THERAPY SYSTEM	T1040 aka AUrawave
Manufacturer	Counter Scientific	Endurance Therapeutics
Power Source	3.0 v（2*1.5vAAA	4.5 v（3*1.5vAAA batteries）
Method of Line Current Isolation	Use resistance to isolate	Use transformer to isolate
Patient Leakage Current	N/A	N/A
Normal Condition（μA）	N/A	N/A
Single Fault Condition（μA）	N/A	N/A
Average DC current through electrodes when device is on but	0μA	0μA
Numbers of Output Modes	3 modes (A,B,C)	10modes (Mode1, Mode2, Mode3, Mode4, Mode5, Mode6, AUTO1, AUTO2, AUTO3, AUTO4)

Number of Output Channels	Synchronous or	2 Synchronous	1 Synchronous
	Method of Channel	Parallel connection	N/A
Regulated current or regulated voltage?		Regulated voltage	Regulated voltage

Parameter		**Subject Device K150277**	**Predicate Device K124055**
Mode or Program Name		PAIN THERAPY SYSTEM，	ELECTRO THERAPY PAIN RELIEF，T1040
Waveform（e.g. positive-going, reverse, biphasic）		Positive-going, Reverse and	Positive-going, Reverse and Biphasic
Shape(e.g., spike, rectangular, square wave)		square wave	square wave
Maximum Output Voltage （Volts）（+/-15%）		88vp @500Ω (Mode B has max)	40.7vp @500Ω
		102vp @2kΩ	105.1vp @2kΩ
		106vp @10kΩ	154.1vp @10kΩ
Maximum Output Current （+/-15%）		176mA @500Ω (Mode B has max)	81.4mA @500Ω
		51.0mA @2kΩ	52.5.0mA @2kΩ
		10.6mA @10kΩ	15.4mA @10kΩ
Duration of primary phase		0	0
Pulse Duration		170 μs	200 μs
Frequency		1-136 Hz	1-250 Hz
For multiphase waveforms only:	Symmetrical phases	N/A	
	Pulse Duration	N/A	
Net charge (micro coulombs μC) per pulse) (If zero, state method of achieving zero net charge.)		1.63μC @500Ω	1.9μC @500Ω
Maximum Phase Charge（μC）		29.9μC @500Ω	16.9μC @500Ω
Maximum Current Density (mA/cm2, r.m.s.)		8.31mA/cm^2 @500Ω	3.84mA/cm^2 @500Ω
Maximum Average Current (average absolute value), mA		2.22mA	1.28mA

Maximum Average Power Density (using smallest electrode conductive surface area)	0.115mW/cm^2 @500Ω	0.039mW/cm^2 @500Ω

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Counter did not conduct, nor rely upon, clinical tests to determine substantial equivalence of the ***Pain Therapy System Model PTS-II*** vs. the predicate. Non-clinical testing was performed in order to validate the design according to the company's specified design requirements, and to assure conformance with the following voluntary design standards:

a. **EMC and electrical safety**

ANSI/AAMI ES60601-1:2005+Corr.1(2006)+Corr.2(2007) general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-06 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

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 disturbances - requirements and tests. (General II (ES/EMC))

b. **Biocompatibility**

The electrode pads are the only body contacting parts. They have been FDA cleared under K132588.

c. **Software**

Based upon the test results it was concluded that the software performs within specifications and is safe to the stated intended use. Since a permanent hazard analysis is implemented in the software development process, and due to the clear software architecture, it is believed that the test protocol sufficiently verifies the software's main functional operation.

d. **Cleaning**

The cleaning instructions as described the Instruction Manual have been tested to be sufficient. Testing involved validation of the manual cleaning method as per the instructions. All testing concluded that that the Pain Therapy System can be cleaned by the use of the methods described in the Instruction Manual.

8. Conclusions:

The Counter ***Pain Therapy System, Model PTS-II*** has the same intended use and

technological characteristics as the predicate device. Moreover, bench testing and safety report documentation demonstrate that the submitted device could maintain the same safety and effectiveness as that of predicate device. In the other words, the differences do not affect the intended use and do not raise any new questions of safety or effectiveness or alter the fundamental scientific technology of the device. Thus, the Counter ***Pain Therapy System, Model PTS-II*** is substantially equivalent to the predicate device.