510(k) Summary per 21 CFR; 807.92

AUG 2 0 2012

510(k) # K120500

510(k) SUBMITTER:	Hollywog, LLC 2830 Amnicola Highway Chattanooga, TN 37406
ESTABLISHMENT REGISTRATION:	3008585473
CONTACT:	Michael W. Treas Chief Compliance Officer
DATE PREPARED:	August 16, 2012
PROPRIETARY NAME:	The Pain Pilot™ (a.k.a. Pain Pilot™) / WiTouch™
PANEL:	Neurology
REGULATION NUMBER:	CFR Title 21, 882.5890
CLASSIFICATION:	Class II
PRODUCT CODE:	NUH
COMMON NAME:	Transcutaneous electrical nerve stimulator for pain relief intended for over the counter use

Description:
The device is a battery powered over the counter transcutaneous electrical nerve stimulator with a wireless remote control feature. The general purpose of the device is to apply an electrical stimulus to integral electrodes that are applied to a user's lower back to relieve pain. The device includes a current generator and permanently-affixed electrodes with user replaceable single patient use hydrogel pads (gel-pads) that may be reused for a limited number of reuses. The number of reuses of the gel-pads vary person-to-person dependent upon skin type, oils and pH levels. One side of the adhesive gel-pad adheres to the electrode, and the other side adhere the device to the healthy intact skin of the user's lower back to provide an analgesic electrical stimulus to the painful area. The user controls are located on a hand-held wireless remote control commonly referred to as a Key-fob. The user controls are simple straight-forward power on/off and electrical stimulus intensity up/down.

Indication for Use:
The device is for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

Intended Use:
The intended use is to provide approximately thirty minutes of analgesic electrical stimulus to reduce the perception of pain by electrically stimulating peripheral nerves across healthy intact skin of the user's lower back.

Accessories:

The device utilizes hydrogel pads (gel-pads) for achieving the indications for use and intended use. The composition of the gel-pads is common materials found in the electrode industry. The uniqueness of the gel-pads is in the shape. The maximum average power density of the electrodes with the gel-pads applied is less than 0.25 watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns which is consistent with the referenced predicate devices.

Substantially Equivalent Predicate Devices

Predicate Devices	*510(k)#*	*Proprietary Name*	*Device Classification Name(s), Regulation Number(s), Classification(s) and Product Code(s).*
#1	K110068	PM3030™	CFR Title 21, Sec. 882.5890, Class II, NUH
#2	K090042	Painmaster™ MCT Patch	CFR Title 21, Sec. 882.5890, Class II, NUH
#3	K060846	T1040™	CFR Title 21, Sec. 882.5890, Class II, NUH, NGX

The predicate devices PM3030™ and T1040™ utilize flexible wires between the electrodes and the electrical stimulus generator; thus, increases the indications for use to the lower back and to body surfaces with greater ranges of motion (e.g., knee, shoulder, elbow, and hip). The indications for use for the predicate device Painmaster™ MCT Patch is solely for application to the lower back; same as The Pain Pilot™ / WiTouch™ device.

The intended design of The Pain Pilot™ / WiTouch™ device limits the application for use to the anatomical site of the back. The design includes carbon rubber electrodes that are intended for reuse and are permanently-affixed to a rigid surface of the electrical stimulus generator. The unique connection makes the electrodes integral to the generator. The connection and shape of the electrodes limit application of the device to the contours of the back. These unique characteristic of the integral electrodes are insignificant as it relates to safety and effectiveness, and is not critical to the intended use between the device and the referenced predicate devices.

The referenced predicate devices utilize affixed buttons as the sole method to control the electrical stimulus generator on/off and intensity up/down. The Pain Pilot™ / WiTouch™ device utilizes a wireless remote control radio frequency transceiver to control the electrical stimulus generator on/off and intensity up/down. The transceiver operates in the ISM radio frequency band for wireless medical technology. This uniqueness of controlling the electrical stimulus generator by utilizing a radio frequency transceiver is insignificant as it relates to safety and effectiveness, and is not critical to the intended use between the device and the referenced predicate devices.

The characteristics of the analgesic electrical stimulus between the device and the referenced predicate devices are substantially equivalent as it relates to safety and effectiveness.

510(k) Summary per 21 CFR 807.92(c)

510(k) # K120500

Substantial Equivalence

510(k) Number		K120500	K110068	K090042	K060846
Device Name and Model		The Pain Pilot™	PM3030™	Painmaster MCT Patch	T1040™
Manufacturer		Hollywog, LLC	Omron Healthcare, Inc.	Newmark, Inc.	Endurance Therapeutics
TENS Device Power Source (DC battery)		Battery 1.5VDC (2-Alkaline AAA)	Battery 1.5VDC (3-Alkaline AAA)	No replaceable bonded battery to micro circuit chip	Battery 1.5VDC (2-Alkaline AAA)
Number of Output Modes		4	3	1	10
Number of Output Channels:	Synchronous or Asynchronous?	1 Channel, Asynchronous - Biphasic	1 Channel, Asynchronous - Biphasic	1 Channel, Monophasic Microcurrent	1 Channel, Asynchronous - Biphasic
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	Yes
Automatic Shut Off?		Yes	Yes	Yes	Yes
User Override Control?		Yes	Yes	Yes	Yes
Indicator Display:	On/Off Status?	Yes	Yes	Yes	Yes
	Low Battery?	Yes	Yes	No	Yes
	Voltage/Current Level?	No	Yes	No	Yes
Timer Range (minutes)		Nonadjustable 30 minutes	Nonadjustable 30 minutes	Nonadjustable Continuous up to 4 - 5 days	Nonadjustable 15 minutes
Weight (lbs., oz.)		4.8 oz. w/ batteries included	2.1 oz. w/ batteries included	2.0 oz. w/ battery included	3.1 oz.
Dimensions (in.) [W x H x D]		7.5"(W) x 3.5(H)" x 0.7"(D)	2.17" x 3.74" x 0.74	unspecified	5.91" x 2.68" x 1.02"
Housing Material and Construction		ABS plastic	ABS plastic	unspecified	unspecified
Compliance with U.S. FDA Title 21 CFR 898 Electrode Lead Wire Performance Standard?		Yes	Yes	Yes	Yes
For multiphasic	Symmetrical phases?	No	No	Yes	No
	Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	120µs - 480µs	unspecified	unspecified	4.1µs - 500µs
Maximum Current Density, (mA/cm², r.m.s.)		0.12mA @500Ω	0.095mA @500Ω	unspecified	2.71mA @500Ω
Maximum Average Current (average absolute value), mA		1.6mA @500 Ω	3.5mA @500 Ω	unspecified	
Maximum Average Power Density, (W/cm²), (using smallest electrode conductive surface area)		0.69mW/cm² @500Ω	89mW/cm² @500Ω	unspecified	5.35mW/cm² @500Ω

Declarations of Conformity
The device complies with the following FDA recognized standards:

FDA Recognized Number 5-4, IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 1988 Amendment 1, 1991-11, Amendment 2, 1995. (General)

FDA Recognized Number 5-60, IEC 60601-1-2 Int. 1 Third Edition/I-SH 01:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests, Interpretation Sheet. (General)

FDA Recognized Number 5-41, Medical electrical equipment – Part 1-4: General requirements for safety- Collateral standard: Programmable electrical medical systems, edition 1.1. (General)

FDA Recognized Number 17-5, IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment – Part 2-10: Particular requirements for the safety of nerve and muscle stimulators. (Neurology)

FDA Recognition Number 2-156: AAMI/AMSI/ ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. (Biocompatibility)

FDA Recognition Number 2-153 (Electrodes) ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)

FDA Recognized Standard 2-173 (Electrodes) Recognition Number 2-173: AAMI / ANSI / ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization. (Biocompatibility)

Truthful and Accurate Statement
A statement was included in the Premarket Notification attesting to the truthfulness and accuracy of the information provided.

Further Information
In the event that additional information is required, please contact:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 20 2012

Hollywog, LLC
c/o Mr. Michael Treas
Chief Compliance Officer
2830 Amnicola Highway
Chattanooga, TN 37406

Re: K120500
Trade/Device Name: The Pain Pilot™ (a.k.a. Pain Pilot™) / WiTouch™
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: July 31, 2012
Received: August 1, 2012

Dear Mr. Treas:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K120500**

Device Names: **The Pain Pilot™ (*a.k.a. Pain Pilot™*) / WiTouch™**

Indications for Use:

The device is for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___√___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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