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

September 22, 2017

Hollywog LLC
Michael Treas
Chief Compliance Officer
2830 Amnicola Highway
Chattanooga, Tennessee 37406

Re: K171599
Trade/Device Name: WiTouch Pro, WiTouch, Neubac
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NYN
Dated: August 22, 2017
Received: August 23, 2017

Dear Michael 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 contact the Division of Industry and Consumer Education (DICE) 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 (DICE) 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,

William J. Heetderks -S
2017.09.22 11:06:27 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171599

Device Name
WiTouch Pro, WiTouch, Neubac

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

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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5. 510(k) Summary

5.1

510(k) NUMBER:	K171599
510(k) SUBMITTER:	Hollywog, LLC 2830 Amnicola Highway Chattanooga, TN 37406
ESTABLISHMENT REGISTRATION:	3008585473
CONTACT:	Michael W Treas Chief Compliance Officer, Regulatory Affairs and Quality Assurance
TELEPHONE:	(423) 305-7778
DATE PREPARED:	July 20, 2017
PROPRIETARY NAMES:	WiTouch Pro / WiTouch / Neubac
PANEL:	Neurology
REGULATION NUMBER:	CFR Title 21, 882.5890
CLASSIFICATION:	Class II
PRODUCT CODES:	NUH, NYN
COMMON NAME:	Transcutaneous electrical nerve stimulator for pain relief
CLASSIFICATION NAME:	Stimulator, Nerve, Transcutaneous, Over-The-Counter, Stimulator, Electrical, Transcutaneous, For Arthritis
PREDICATE DEVICE:	WiTouch Pro K120398

5.2 Device Description

The second-generation WiTouch Pro (a.k.a. WiTouch/Neubac) device is a battery powered transcutaneous electrical nerve stimulator (TENS) device for relieving back pain. The device is comprised of a TENS generator with integral electrodes, two replaceable "AAA" size batteries, replaceable electroconductive hydrogel pads (Gel Pads), a Mobile App to control the TENS device via Bluetooth® connection, which installs to Apple® iOS® 9.0 or higher or Android® 4.4 or higher smartphone platforms. Additionally, the TENS intensity may be increased or decreased using onboard mechanical buttons on the TENS unit enclosure. The TENS device offers an optional handheld wireless remote control via Radio Frequency (RF) connection which is sold separate and comes with one replaceable CR2032 Lithium-ion coin battery.

The device accessories are the replaceable Gel Pads, the Mobile App, and the optional wireless handheld remote control. The Gel Pads serve to gently adhere the TENS unit to a user's skin on the lower back, and serves to dissipate electrical stimulation across the surface area of the electrode. The Gel Pads are intended for single person use with the number of uses dependent upon skin type, oils, and pH levels.

The TENS unit adheres to the user's lower back across the spine in the area where pain is perceived. Once placed, a user can choose from four 30-minute preprogrammed stimulation output modes, and the level of intensity that is most comfortable. The preprogrammed modes are identified as WiTouch Pro Exclusive, High Frequency, Low Frequency, and High-Low Combo.

Accessories:

- Pairs of replaceable hydrogel pads (Gel Pads)
- Mobile Medical Application control using a smartphone via Bluetooth® connection (Apple® iOS® or Android® platforms)
- Handheld wireless Remote Control.

5.3 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 lower back.

5.4 Indications for Use

To be used for temporary relief of pain associated with sore and aching muscles in the back due to strain from exercise or normal household and work activities and relief of pain of the upper and lower back associated with arthritis.

5.5 Non-Clinical Testing

The verification, validation, performance, and human factors data presented in this 510(k) submission demonstrate the second-generation WiTouch Pro TENS device is substantially equivalent to the predicate device.

5.6 Predicate Device

The predicate device is the first-generation WiTouch Pro TENS device which cleared to market in 510(k) K120398. The predicate device is substantially equivalent to the subject device identified in this 510(k) Summary which is the second-generation WiTouch Pro device. The differences between the predicate device and the subject device do not raise new questions about safety or effectiveness. The subject device is as safe and effective as the predicate device. The following table is a characteristics comparison between the subject device and the predicate device.

5.6.1 Characteristics

Characteristic	**Subject Device – K# TBD** **Hollywog, LLC** **WiTouch® Pro/WiTouch®/Neubac® Models**	**Predicate Device - 510(k)** **K120398** **Hollywog, LLC** **WiTouch® Pro** **Model 11.1500**
Indications for Use	To be used for temporary relief of pain associated with sore and aching muscles in the back due to strain from exercise or normal household and work activities and relief of pain of the upper and lower back associated with arthritis.	The WiTouch® Pro Transcutaneous Electrical Nerve Stimulator Device is used for the symptomatic relief and management of chronic intractable back pain and relief of pain of the upper and lower back associated with arthritis. It is also used for adjunctive treatment for post-surgical and post-trauma acute back pain.
Product Code	NUH, NYN *(OTC Use)*	GZJ, NYN *(Prescription Use)*
Anatomical Location	Upper and lower back	Upper and lower back
Power Source(s)	TENS Unit (2) "AAA" Alkaline Batteries Remote Control (1) "CR 2032" Lithium-ion coin battery	TENS Unit (2) "AAA" Alkaline Batteries Remote Control (1) "CR 2032" Lithium-ion coin battery
Low battery indicator	Yes	Yes
Average DC current through electrodes when the device is on but no pulses are being applied (µA)	0	0

Number of Output Preprogrammed Modes	4 4 - TENS	1 1 - TENS
Number of Output Channels	1	1
Regulated Current or Regulated Voltage?	Voltage	Voltage
Waveform	Asymmetrical biphasic (0 net DC charge)	Asymmetrical biphasic (0 net DC charge)
Amplitude	0 – 80mA (Measured @ 500 ohm load)	0 – 80mA (Measured @ 500 ohm load)
Pulse Width	120 - 250µs (Preprogrammed)	120 - 240µs (Preprogrammed)
Pulse Rate	2 – 120 Hz	5 – 120 Hz
Software/Firmware/ Microprocessor Control?	Yes	Yes
Automatic Overload Trip?	No	No
Automatic No-Load Trip?	No	No
Automatic Shut Off?	Yes	Yes
User Override Control?	Yes Off button immediately stops treatment	Yes Off button immediately stops treatment
Indicator Display	On/Off Status? Yes Low Battery? Yes Voltage/Current Level? No	On/Off Status? Yes Low Battery? Yes Voltage/Current Level? No
Timer Range	Nonadjustable 30 minutes	Nonadjustable 30 minutes 42 seconds
Compliance with 21 CFR 898	N/A, device does not contain electrode lead wires or patient cables.	N/A, device does not contain electrode lead wires or patient cables.
Weight (lbs., oz.)	4.8 oz. w/ batteries included	4.8 oz. w/ batteries included
Dimensions (in.) [W x H x D]	7.5 (w) x 3.5 (h) x 0.7 in (d)	7.5 (w) x 3.5 (h) x 0.7 in (d)

Voluntary Standards	• FDA Recognition Number 13-79: IEC 62304 Edition 1.1 2015-06 • FDA Recognition Number 19-4: ANSI/AAMI ES60601-1:2005 Ed. 3 + C1:2009 + A1:2012 • FDA Recognition Number 19-16/19-7: ANSI/AAMI HA60601-1-11:2015/2011 • FDA Recognition 19-8. IEC 60601-1-2:2014 Ed. 4 • FDA Recognition Number 19-14: IEC 60601-1-11 Edition 2.0 2015-01 • FDA Recognition Number 17-11: IEC 60601-2-10 Edition 2.0 2012-06 • FDA Recognition Number 5-40: ISO 14971 Second edition 2007-03-01	• AAMI ANSI ES60601-1:2005/(R)2012 And A1:2012 • IEC 60601-1-2 Edition 2014-02 • IEC 60601-1-11 Edition 1.0 2010-04 • IEC 60601-2-10 Edition 1.0 2012-06 • AAMI/ANSI/ISO 10993-5:2009 • AAMI/ANSI/ISO 10993-10:2010

5.7 Conclusion

The basis for substantial equivalence for the referenced predicate device and for the second-generation WiTouch Pro TENS device is non-clinical data and conformity with recognized standards.

Clinical testing was not required to support substantial equivalence for the second-generation WiTouch Pro TENS device. This is due to the intended use is well established and understood, and the hardware and software verification and validation demonstrate that the second-generation WiTouch Pro TENS device performs comparably to the predicate device that is marketed for the same intended use.

Based on the performance testing and the similarities of the indications for use and the technological characteristics, it can be concluded that the second-generation WiTouch Pro TENS device is as safe and effective as, and substantially equivalent to, the predicate device.