



Food and Drug Administration
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December 22, 2015

Bayer Healthcare, LLC
William Walsh
Director, Us Regulatory Affairs
100 Bayer Boulevard
Whippany, New Jersey 07981-0915

Re: K152852

Trade/Device Name: Aleve Direct Therapy (Aleve Direct Therapy Tens Device)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: August 25, 2015
Received: September 29, 2015

Dear Mr. Walsh:

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,

William J. Heetderks -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

Indications for Use

510(k) Number (if known)

K152852

Device Name

ALEVE Direct Therapy TENS Device

Indications for Use (Describe)

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.

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.

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510(K) SUMMARY

I. SUBMITTER

Company Name: Bayer HealthCare LLC, Consumer Care
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Whippany, NJ 07981-0915

Contact Person: William R. Walsh, R.Ph.
Phone: (862)-404-6355
bill.walsh@bayer.com

Date Prepared: September 29, 2015

II. DEVICE

Trade Name: ALEVE Direct Therapy
Common Name: Transcutaneous electrical nerve stimulator for pain relief intended for over the counter use (TENS)
Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
Device Classification: 21 CFR 882.5890, Class II, NUH

III. PREDICATE DEVICE

Predicate Devices: The Pain Pilot™ (a.k.a. Pain Pilot™) / WiTouch®
K120500
21 CFR 882.5890, Class II, NUH

IV. DEVICE DESCRIPTION

The ALEVE Direct Therapy device is a battery powered transcutaneous electrical nerve stimulator (TENS) for applying an electrical current to electrodes on a patient's skin to relieve pain. The device reduces the perception of pain by electrically stimulating peripheral nerves across the skin. The design of the device limits the application for use to the anatomical site of the back.

The device is comprised of a TENS unit with integral electrodes, one pair of replaceable electroconductive hydrogel pads, batteries for the remote and TENS unit, and a remote control. The user can turn the device on/off by pressing a button on the TENS unit. The hydrogel pads are adhesive and gently adhere the TENS unit to the user's skin on the lower back. There is also a remote control for the device, which the user turns on/off, and by which the user adjusts the intensity of stimulation.

V. INDICATIONS FOR USE

The ALEVE Direct Therapy is indicated 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

This product is nearly identical to the predicate device except for minor differences: trade name, color of the non-conductive area of the integral silicone electrodes (change to ultramarine blue), non-significant modifications to the labeling and label designs, and an updated version of the software due to non-significant revisions made during the marketing of the PainPilot (Neubac) / WiTouch compared to the version cleared in 2012. All device components and accessories, basic unit characteristics, and output specifications are the same as the predicate device.

A comparison of the Basic Unit Characteristics is provided below.

Basic Unit Characteristics Comparison

Characteristic	Bayer HealthCare, LLC ALEVE Direct Therapy Subject of this Submission	Hollywog Pain Pilot (Neubac) / WiTouch K120500	Comparison
Power Source(s)	Battery Powered	Battery Powered	IDENTICAL
Number, Size, and Type of Batteries	2 AAA 1.5v DC batteries (TENS device) 1 Lithium coin battery 3.0v DC (wireless remote)	2 AAA 1.5v DC batteries (TENS device) 1 Lithium coin battery 3.0v DC (wireless remote)	IDENTICAL
Average DC current through electrodes when device is on but no pulses are being applied (µA)	0	0	IDENTICAL
Number of Output Modes	1	1*	IDENTICAL
Number of Output Channels	1	1	IDENTICAL
Regulated Current or Regulated Voltage?	Voltage	Voltage	IDENTICAL
Software/Firmware/Microprocessor Control?	Yes	Yes	IDENTICAL
Automatic Overload Trip?	No	No	IDENTICAL
Automatic No-Load Trip?	No	No	IDENTICAL
Automatic Shut Off?	Yes	Yes	IDENTICAL
User Override Control?	Yes	Yes	IDENTICAL
Indicator Display	On/Off Status? Yes Low Battery? Yes Voltage/Current Level? No	On/Off Status? Yes Low Battery? Yes Voltage/Current Level? No	IDENTICAL
Timer Range	Nonadjustable 30 minutes 42 seconds	Nonadjustable 30 minutes 42 seconds	IDENTICAL
Compliance with	• ISO 14971:2007	• ISO 14971:2007	Substantially Equivalent.

Characteristic	Bayer HealthCare, LLC ALEVE Direct Therapy Subject of this Submission	Hollywog Pain Pilot (Neubac) / WiTouch K120500	Comparison
Voluntary Standards	<ul style="list-style-type: none"> • 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 10993-1:2009/(R) 2013 • AAMI/ANSI/ISO 10993-5:2009 (R)2014 • AAMI/ANSI/ISO 10993-10:2010 	<ul style="list-style-type: none"> • IEC 60601-1: 1995 • IEC 60601-1-2: 2001 • IEC 60601-1-4:2000 • IEC 60601-2-10: 2001 • ISO 10993-1:2009 • ISO 10993-5:2009 • ISO 10993-10:2010 	Current device complies with updated versions of standards.
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.	IDENTICAL
Weight (lbs., oz.)	4.8 oz. w/ batteries included	4.8 oz. w/ batteries included	IDENTICAL
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)	IDENTICAL
Patient Contacting Materials including Housing Materials and Construction	Hydrogel (Gel pads) ABS plastic enclosure (Housing) Integral silicone electrodes with conductive (carbon rubber) area and non-conductive area with ultramarine blue colorant (CAS # 57455-37-5)	Hydrogel (Gel pads) ABS plastic enclosure (Housing) Conductive (carbon) silicone electrodes Non-conductive area of the integral silicone electrodes, of green color	Substantially Equivalent. The safety of this colorant has been demonstrated (Section 12, Biocompatibility). A difference in colorant does not affect the performance characteristics of the device, and the difference does not raise new questions of safety or effectiveness.

VII. PERFORMANCE DATA

Conformance with the following voluntary, FDA-recognized standards is provided in this 510(k) submission:

- Recognition Number 5-40: ISO 14971 Second Edition 2007-03-01, Medical devices - application of risk management to medical devices.
- Recognition Number 19-4: AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (consolidated text) Medical electrical equipment - part 1: General requirements for basic safety and essential performance.
- Recognition Number 19-8: IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic disturbances - requirements and tests.
- Recognition Number 19-14: IEC 60601-1-11 Edition 1.0 2010-04, 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.
- Recognition Number 17-11: IEC 60601-2-10 Edition 2.0 2012-06, Medical electrical equipment - part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
- Recognition Number 2-156: AAMI/ANSI/ISO 10993-1:2009/(R) 2013, Biological evaluation of medical devices - part 1: Evaluation and testing within a risk management process.
- Recognition Number 2-153, AAMI/ANSI/ISO 10993-5:2009/(R) 2014, Biological evaluation of medical devices - part 5: Tests for *in vitro* cytotoxicity.
- Recognition Number 2-173, AAMI/ANSI/ISO 10993-10:2010, Biological evaluation of medical devices - part 10: Tests for irritation and skin sensitization.

Performance Testing

Data in support of the device waveform, and verification of output characteristics, was provided in this submission.

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation in accordance with a Moderate level concern device was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Usability

A 15 subject usability study was conducted by Hollywog and reported to the FDA during the review of predicate K120500, based on feedback provided from the FDA during Pre-IDE submission correspondence. The submitter has a right of reference to this study, as the devices

and labeling are sufficiently similar, in support of the usability of the ALEVE Direct Therapy device.

VIII. CONCLUSIONS

The electrical safety, EMC, biocompatibility, software verification and validation, basic unit characteristics, and output specifications information provided in the 510(k) submission is sufficient to demonstrate substantial equivalence to the predicate device. As the ALEVE Direct Therapy TENS device is nearly identical to the predicate device, with identical indications for use and essentially identical technological characteristics, the ALEVE Direct Therapy TENS device is substantially equivalent to the predicate device.