March 7, 2018

Bayer HealthCare LLC
Verna Mecadon
Director, Regulatory Affairs
100 Bayer Boulevard
Whippany, New Jersey 07981-0915

Re: K171802
Trade/Device Name: ALEVE® Direct Therapy®
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NYN
Dated: February 7, 2018
Received: February 7, 2018

Dear Verna Mecadon:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2018.03.07 12:45:37 -05'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171802

Device Name
ALEVE® Direct Therapy®

Indications for Use *(Describe)*
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. For symptomatic relief and management of chronic, intractable pain and relief of pain 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.

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2. 510(k) SUMMARY

510(k) NUMBER:	K171802
510(k) SUBMITTER:	Bayer HealthCare LLC 100 Bayer Boulevard Whippany, NJ 07981
CONTACT:	Verna Mecadon Director, Regulatory Affairs Verna.mecadon@bayer.com
DATE PREPARED:	February 7, 2018
PROPRIETARY NAME:	ALEVE® Direct Therapy®
PANEL:	Neurology
REGULATION NUMBER:	CFR Title 21, 882.5890
CLASSIFICATION:	Class II
PRODUCT CODES:	NUH, NYN
COMMON NAME:	Transcutaneous electrical nerve stimulator (TENS) for pain relief intended for over the counter use

2.1 Predicate Devices [807.92(a)(3)]

- ALEVE Direct Therapy TENS, first-generation (K152852)
- Chattem SmartRelief (K131159)

2.2 Device Description [807.92(a)(4)]

The ALEVE® Direct Therapy® device is a battery powered transcutaneous electrical nerve stimulator (TENS) device for relieving lower back pain. The device is comprised of a TENS generator with integral electrodes, two replaceable "AAA" size batteries, replaceable electroconductive hydrogel pads (Gel Pads), and 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 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.

2.3 Intended Use and Indications for Use [807.92(a)(5)]

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.

Indications for Use

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. For symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

2.4 Comparison of Technological Characteristics with the Predicate Devices [807.92(a)(6)]

The ALEVE® Direct Therapy® is substantially equivalent in design and labeling to the primary predicate device and secondary predicate device. As demonstrated in **Table 2.1**, the ALEVE Direct Therapy TENS device is identical to the primary predicate device, Predicate 1, with respect to intended use, outer dimensions of the TENS unit, On/Off button, electrodes, materials, hand-held remote control, RF communication, and pulse amplitude. The differences between the subject device and primary predicate device, Predicate 1, are the expanded indications for use, three additional treatment programs consisting of similar ranges of output specifications, up/down (+/-) buttons on the outer TENS cover, the Mobile App using Bluetooth communication, and a minor difference in the ranges for pulse duration and pulse frequency. Additionally, as shown in **Table 2.1**, the subject device is identical to the secondary predicate, Predicate 2, with respect to indications for use and substantially equivalent to Predicate 2 with output specifications of pulse amplitude, pulse frequency, and pulse duration. Non-clinical testing performed on the ALEVE® Direct Therapy® is sufficient to demonstrate that the subject device is as safe and effective as the legally marketed predicate devices. The technological and labeling differences do not raise new or different questions about safety or effectiveness. ALEVE® Direct Therapy® second-generation device is substantially equivalent to the predicate devices.

Table 2.1 Technological Characteristics

Device Feature	Bayer HealthCare, **ALEVE Direct Therapy** (2nd generation) Subject Device	Bayer HealthCare, **ALEVE Direct Therapy** Primary Predicate (Predicate 1)	Chattem, **SmartRelief** Secondary Predicate (Predicate 2)
510(k) Number	K171802	K152852	K131159
Regulation Number	CFR Title 21, 882.5890		
Product Code	NUH, NYN	NUH	NUH, NYN
Intended Use	Transcutaneous Electrical Nerve Stimulator for Pain Relief		
Rx and/or OTC	OTC	OTC	OTC
Indications for Use	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. Symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	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.	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. Symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.
Anatomical Location	Lower back	Lower back	Various locations (including lower back)
Power Source	Battery-powered	Battery-powered	Battery-powered
Control System	Microprocessor	Microprocessor	Microprocessor
Operating Mechanism	On-board buttons, remote control, and smartphone mobile app	Remote control	On-board buttons
Average DC current through electrodes when the device is on but no pulses are being applied (μA)	0	0	0
Waveform	Asymmetrical biphasic	Asymmetrical biphasic	Asymmetrical biphasic
Shape	Rectangular	Rectangular	Rectangular
Number of Output TENS Modes	4	1	1
Number of	1	1	1

Output Channels			
Regulated Current or Regulated Voltage?	Voltage	Voltage	Voltage
Pulse Duration (µs)	120-250 µs	120-240 µs	30 - 220µs
Pulse Frequency (Hz)	2-120Hz	5-120hz	1 – 100 Hz
Pulse Amplitude (mA)	0 – 110mA (Measured peak @ no load.) 0 – 80mA (Measured @ 500 ohm load)	0 – 110mA (Measured peak @ no load.) 0 – 80mA (Measured @ 500 ohm load)	0 – 63mA (Measured peak @ 500 ohm load)
Automatic Overload Trip?	No	No	No
Automatic No-Load Trip?	No	No	No
Automatic Shut Off?	Yes	Yes	Yes
User Override Control	Yes, Off button stops treatment immediately	Yes, Off button stops treatment immediately	Yes, Off button stops treatment immediately
Indicator Display	On/Off Status? Yes Low Battery? Yes Voltage/Current Level? No	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	Nonadjustable, 30 minutes
Voluntary Standards	• FDA Recognition Number 19-4. ANSI/AAMI ES60601- 1:2005 Ed. 3 + C1:2009 + A1:2012 • 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 19-4. ANSI/AAMI ES60601- 1:2005 Ed. 3 + C1:2009 + A1:2012 • 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	• . ANSI/AAMI ES60601-1:2005/®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

	• FDA Recognition Number 5-40: ISO 14971 Second edition 2007-03-01 • FDA Recognition Number 13-79: IEC 62304 Edition 1.1 2015-06	• FDA Recognition Number 2-173, AAMI/ANSI /ISO 10993-10:2010 • FDA Recognition Number 5-40: ISO 14971 Second edition 2007-03-01	
Compliance with 21 CFR 898	Not applicable, device not contain electrode lead wires or patient cables.	Not applicable, device not contain electrode lead wires or patient cables.	Not applicable, device not contain electrode lead wires or patient cables.
Weight (lbs., oz.)	~4.8 oz. with batteries included	~4.8 oz. with batteries included	~4.8 oz. with batteries included
Dimensions (in.) [WxHxD]	7.5(w) x 3.5 (h) x 0.7in. (d)	7.5(w) x 3.5 (h) x 0.7in. (d)	64 x 38x 13mm

2.5 Performance Data [807.92(b)(1), (b)(2)]

Non-Clinical Testing Summary

The non-clinical bench and safety testing and assessments included:

- Performance verification consisting of unit level testing, system testing, and software verification and validation
- Usability Engineering testing
- Biocompatibility requirements per ISO 10993-1
- Electrical Safety and Electromagnetic Compatibility testing

The verification, validation, electrical safety testing, electromagnetic compatibility testing, and human factors data presented in this 510(k) submission demonstrate the second-generation ALEVE® Direct Therapy® TENS device met the established specifications and its intended use. In addition, the testing demonstrated that the subject device does not raise new or different questions of safety or effectiveness when compared to the legally-marketed predicate devices.

Clinical Testing Summary

Not applicable. Clinical testing was not performed to support this 510(k) submission.

2.6 Conclusion [807.92(b)(3)]

The basis for substantial equivalence for the second-generation ALEVE® Direct Therapy® TENS device and the predicate devices is non-clinical data and conformity with recognized standards. Clinical testing was not required to support substantial equivalence for the second-generation ALEVE Direct Therapy TENS device as the intended use of TENS is well-established and the hardware and software verification and validation demonstrate that the subject device

performs comparably to the predicate devices that are 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 ALEVE Direct Therapy TENS device is as safe and effective as, and substantially equivalent to the predicate devices.