January 31, 2020

BioElectronics Corporation
Sree Koneru, Ph.D.
VP, Product Development
4539 Metropolitan Ct
Frederick, Maryland 21704

Re: K192234
Trade/Device Name: ActiPatch®
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: PQY
Dated: November 1, 2019
Received: November 4, 2019

Dear Dr. Koneru:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Vivek Pinto, Ph.D.
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K192234

Device Name
ActiPatch

Indications for Use *(Describe)*
Adjunctive treatment of musculoskeletal pain

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

1. **Submitter's Name:** BioElectronics Corporation

2. **Address:** 4539 Metropolitan Court,
Frederick, MD 21704, USA
Phone: 301-500-2061
Fax 301-874-6935

Contact Person: Sree N Koneru, Ph.D.
VP, Product Development

3. **Date Prepared:** January 3, 2020

4. **Trade Name:** ActiPatch®

5. **Common Name** Nonthermal Shortwave Therapy

6. **Product Classification:** 21 CFR 890.5290 (b)
Product Code: PQY

7. **Predicate Devices:** Primary Predicate: ActiPatch (K152432)

8. **Description of Device:**

The ActiPatch® device is a pulsed shortwave therapy device. The circuitry consists of low voltage (3 V) digital/analog electronics that control all timing functions to produce the therapeutic radiofrequency (RF) field, where the antenna is placed directly above the therapeutic site. This closed loop system of the antenna, low energy signal generator circuit, and battery power supply, transfers the RF energy to the target tissue as a localized therapy with no far field effects.

9. **Intended Use:** Adjunctive treatment of musculoskeletal pain

10. **Standards**

BS EN 980: 2003 Graphical Symbols For Use In The Labeling of Medical Devices

ISO 13485:2012 Medical Devices: Quality Management Systems

ISO 14971: 2012 Risk Management

BS EN ISO 15223-1:2012 Labeling of Medical Devices

IEC 60601-1:2005+A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety and Essential Performance

IEC 60601 -1-2: 2007 Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

EN 60601-2-3: 2014 Short-Wave Therapy Equipment

EN 60601-2-10: 2015 Safety of Nerve and Muscle Stimulators

MEDDEV 2.7.1 Rev. 4 Clinical Evaluation

MEDDEV 12.2-2 Rev. 2 Post Market Surveillance

11. Summary of technological characteristics:

The ActiPatch® device has the following technological characteristics (Table 1.) The ActiPatch operates at a carrier frequency of 27.12MHz, with a pulse frequency of 1000 Hz and a pulse width of 100 micro-seconds. The duty cycle is therefore 10%. The devices uses a 3v battery as the power source (CR 2032 or CR1632 or CR1620) and produces a peak spatial power density of 73 microWatts/cm^2.

Table 1. Technological characteristics of the ActiPatch® Shortwave Therapy Device

Carrier frequency	27.12MHz
Peak spatial power density	73 microwatts/ cm^2
Pulse rate	1000 pulses per second
Pulsed on duration	100 micro seconds
Power source	Battery CR2032 or CR1632 or CR1620
Antenna size	12cm or 6 cm diameter
Treatment area	110cm^2 or 30cm^2
Weight	9.5 grams
Operation time (lifetime of battery)	720 hours or 360 hours or 168 hours
User Control	On/Off switch or On-only (continuous use) switch
Recommended Treatment Time	Minimum of 12 hours per day, up to 24 hours per day

12.Substantial Equivalence:

ActiPatch has the same intended use as the predicate device, *i.e.*, the application of electromagnetic energy to non-thermally treat pain. The current ActiPatch's technological features are identical to those of the predicate ActiPatch device in K152432 (Table 2). No device modifications have been made to the current ActiPatch, when compared to the predicate ActiPatch device.

The predicate device is indicated for adjunctive treatment of musculoskeletal pain related to: 1) Osteoarthritis of the knee; and 2) Plantar fasciitis of the heel (K152432). The performance data submitted in the premarket notification, including the electrical safety, electromagnetic safety, biocompatibility, and clinical data described in Section 13 below, show that there is no difference in technology between the subject and predicate device, and that the subject ActiPatch is at least as safe and effective as the predicate ActiPatch.

Table 2. Technological characteristics of the ActiPatch® and predicate ActiPatch®.

	ActiPatch	Predicate ActiPatch (K152432)
Indication for Use	Adjunctive treatment of musculoskeletal pain	Adjunctive treatment of musculoskeletal pain related to: (1) plantar fasciitis of the heel; and (2) osteoarthritis of the knee
Technology	Pulsed Shortwave Therapy (Non- thermal Diathermy)	Pulsed Shortwave Therapy (Non- thermal Diathermy)
Product code	PQY	PQY
Regulation	21 CFR 890.5290(b)	21 CFR 890.5290(b)
Classification Name	Shortwave Diathermy	Shortwave Diathermy
Anatomical Site of application	Superficial soft tissue	Superficial soft tissue
How the Energy is coupled	Induction Coil	Induction Coil
Carrier Frequency	27.1 MHz	27.1 MHz

Pulse Duration	100 micro-secs	100 micro-secs
Pulse rate	1000 Hz	1000 Hz
Duty cycle	10%	10%
Power source	3V DC (1 X CR2032 or CR1632 or CR 1620 Lithium Battery)	3V DC (1 X CR2032 Lithium Battery)
Antenna Size	110 cm^2 or 30 cm^2	110 cm^2 or 30 cm^2
Average spatial power density (RMS)	4.4 µWatts/cm^2	4.4 µWatts/cm^2
Specific adsorption rate (W/kg) (Peak)	0.0007 W/kg	0.0007 W/kg
Operation time (battery lifetime)	720 hours or 360 hours or 168 hours	720 hours
Recommended treatment duration (use time) based on clinical evidence	Minimum of 12 hours per day, up to 24 hours per day	Minimum of 12 hours per day, up to 24 hours per day

13.Testing

Non-Clinical/Performance Data:

Electrical safety, electromagnetic safety, biocompatibility testing, and testing in accordance with the special controls of the October 13, 2015 Final Reclassification Order for Nonthermal Shortwave Therapy devices was performed for the ActiPatch.

The ActiPatch was tested for conformity to the following standards and was determined to conform to these standards:

- General Safety and Requirements – Medical Equipment- IEC/EN 60601-1-2
- General Safety and Requirements – Medical Equipment- EN 60601-1:2006

Biocompatibility testing was conducted for the ActiPatch. The skin sensitization test performed in accordance with ISO 10993-10:2010 showed no evidence of an ActiPatch extract causing skin sensitization in guinea pigs. The skin irritation test conducted in accordance with ISO 10993-10:2010 demonstrated that gauze material saturated with extract from the ActiPatch showed no evidence of causing skin irritation in New Zealand white rabbits. The cytotoxicity test performed in accordance with ISO 10993-5:2009 showed that no observable *in vitro* cytotoxicity in L-

929 mouse fibroblast cells that were placed in contact with an extract prepared from ActiPatch.

The testing that was conducted in accordance with the special controls of the October 13, 2015 Final Reclassification Order demonstrated that the ActiPatch performs as intended under anticipated conditions of use. The testing determined and considered the peak output power; the pulse width; the pulse frequency; the duty cycle; the average measured output powered into the RF antenna/applicator; the specific absorption rates in a saline gel test load; the characterization of the electrical and magnetic fields in saline gel test load for each RF antenna and prescribed RF antenna orientation/position; and the characterization of the deposited energy density in saline gel test load.

Clinical Data:

The clinical data in this 510(k) includes results from three IRB approved, randomized, controlled studies. Additionally, usability testing was conducted to support the OTC use of the device.

- A randomized, controlled trial on chronic cervical osteoarthritis (neck pain): This was a randomized, active-treatment controlled study to evaluate the safety and effectiveness of the ActiPatch medical device to reduce the pain level of patients diagnosed with cervical osteoarthritis. The active-treatment control was an NSAID of the Cox-2inhibitor family. There were 200 intent-to-treat patients, out of which 197 completed the four-week study. There were 142 women (71%) and 58 (29%) men in the study, with an average age of 45 years. The primary endpoint for efficacy was reduction in pain (VAS score) while at rest and being active, over four weeks, when compared to the beginning of the study. The results indicate that ActiPatch significantly reduced pain (measured by VAS pain) associated with COA in the device treatment group, and that the treatment differences between device-treatment and NSAID-treatment groups was significant ($p<0.05$).

- A randomized controlled trial on osteoarthritis of the knee: The osteoarthritis of the knee study was a double-blinded, randomized, placebo-controlled study to evaluate the safety and effectiveness of the ActiPatch medical device to reduce the pain level of patients diagnosed with knee osteoarthritis. The placebo treatment was a device that was identical to ActiPatch but did not produce an

electromagnetic field when turned on. There were 66 intent-to-treat patients, out of which 60 patients completed the four-week study. There were 43 women (71.6%) and 17 (16.4%) men in the study, with the following average demographics at baseline: 68 years of age, BMI of 27.4 and disease duration of 12.1 years. The primary effectiveness endpoints were improvements in pain level over the four weeks as measured by the before and after VAS score and WOMAC scores, and the primary safety endpoint was all treatment-related adverse events during the study. The results indicate that ActiPatch significantly reduced pain (measured by VAS pain) associated with KOA in the device treatment group, and that the treatment differences between active and placebo treatment groups was significant ($p<0.05$).

- A randomized controlled trial on plantar fasciitis (heel pain): This was a randomized, double-blinded, placebo-controlled study to evaluate the safety and effectiveness of the ActiPatch medical device to reduce the pain level of patients diagnosed with plantar fasciitis. The placebo treatment was a device that was identical to ActiPatch but did not produce an electromagnetic field when turned on. A total of 70 patients were recruited into the study, and all 70 completed the study. There were 52 women (74.4%) and 18 (25.6%) men in the study, with the following average demographics at baseline: 51.5 years of age, BMI of 31.8 and disease duration of 1.1 years. The primary effectiveness endpoint was the daily morning (AM) VAS score, and the primary safety endpoint was all treatment-related adverse events during the 7-day study. The results indicate that ActiPatch significantly reduced pain (measured by VAS pain) associated with PF in the device treatment group, and that the treatment differences between active and placebo treatment groups was significant ($p<0.05$).

- Usability testing was conducted in 46 men and women over the age of 18 with a wide range of education levels who used the RecoveryRx on the knee, lower back, or shoulder. The testing showed that lay users understand the indications for use and when not to use the device. In addition, the study showed that users understand how to turn the device on, place it correctly on the right part of the body, and how long to use the device.

Conclusion: The non-clinical data, clinical data, and extensive real-world registry data demonstrate that the ActiPatch is at least as safe and effective

as the predicate device and can be used as an over-the-counter device for adjunctive treatment of musculoskeletal pain.

Note: Treatment effects of device use were clinically assessed for up to 4 weeks.