June 28, 2019

BioElectronics Corporation
Sree Koneru, PhD
VP, Product Development
4539 Metropolitan Ct
Frederick, Maryland 21704

Re: K190251
Trade/Device Name: RecoveryRx®
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: ILX
Dated: May 30, 2019
Received: May 31, 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,

Vivek Pinto, Ph.D.
Assistant 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)*
K190251

Device Name
RecoveryRx®

Indications for Use *(Describe)*
Adjunctive treatment of postoperative 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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Section 5: 510(k) Summary

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

2. **Address:** 4539 Metropolitan Court,
Frederick, MD 21704, USA
Phone: 301-874-4890
Fax 301-874-6935

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

3. **Date Prepared:** June 27, 2019

4. **Trade Name:** RecoveryRx® (K190251)

5. **Common Name** Nonthermal Shortwave Therapy

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

7. **Predicate Devices:** Primary Predicate: ActiBand (K022404)
Secondary Predicate: Ivivi (K070541)

8. **Description of Device:**

The RecoveryRx® 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 postoperative 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 RecoveryRx® device has the following technological characteristics (Table 1.) The RecoveryRx 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 RecoveryRx® 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:

RecoveryRx has the same intended use as the predicate device, *i.e.,* the application of electromagnetic energy to non-thermally treat pain. The current RecoveryRx's technological features are similar to those of the predicate devices, ActiBand (K022404) and Ivivi (K070541) as shown in the table below. No modifications have been made to the signal parameters of the RecoveryRx device when compared to the ActiBand predicate device.

RecoveryRx's technological features are identical to those of the ActiBand, with only slight differences that do not affect the technological performance of the device, such as the adoption of an ASIC microchip, compared to larger, discrete circuitry components (both active and passive) in the ActiBand, and a slightly larger antenna in the RecoveryRx. The therapeutic effects of ActiBand® and RecoveryRx are due to the pulsed shortwave signal that is identical between the two devices.

The predicate devices are indicated for treating postoperative conditions (K022404-treatment of edema following blepharoplasty; K070541-adjunctive use in the palliative treatment of post-operative pain and edema in superficial soft tissue). The subject RecoveryRx is identical to the primary predicate and differs from the secondary predicate only in antenna size/pulse rate (Table 2), but does not affect the average spatial power density levels. 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 any differences in technology do not adversely affect the safety and effectiveness of the RecoveryRx compared to the predicates, and that the RecoveryRx is at least as safe and effective as the predicates.

Table 2. Technological characteristics of the RecoveryRx® and predicate devices.

	RecoveryRx	**Predicate ActiBand (K022404)**	**Predicate Ivivi (K070541)**
Indication for Use	Adjunctive treatment of postoperative pain	For the treatment of edema following Blepharoplasty	Adjunctive use in the palliative treatment of post-operative pain and edema in superficial soft tissue.
Technology	Pulsed Shortwave Therapy (Non-thermal Diathermy)	Pulsed Shortwave Therapy (Non-thermal Diathermy)	Pulsed Shortwave Therapy (Non-thermal Diathermy)
Product code	ILX	ILX	ILX
Regulation	21 CFR 890.5290(b)	21 CFR 890.5290(b)	21 CFR 890.5290(b)
Classification Name	Shortwave Diathermy	Shortwave Diathermy	Shortwave diathermy
Anatomical Sites	Superficial soft tissue	Superficial soft tissue	Superficial soft tissue
How the Energy is coupled	Induction Coil	Induction Coil	Induction coil
Carrier Frequency	27.1 MHz	27.1 MHz	27.1 MHz
Pulse Duration	100 µsec	100 µsec	2 msec
Pulse rate	1000 Hz	1000 Hz	Undisclosed on public 510(k) database
Duty cycle	10%	10%	0.4%[1]
Power source	3V DC (1 X CR2032 Lithium Battery)	6V DC (2 X CR2032 Lithium Battery	2x CR2032 batteries
Antenna Size	110 cm^2	110 cm^2	285 cm^2
Average spatial power density (RMS)	4.4 µWatts/cm^2	4.4 µWatts/cm^2	Undisclosed on public 510(k) database
Specific adsorption rate (W/kg) (Peak)	0.0007 W/kg	0.0007 W/kg	Undisclosed on public 510(k) database
Operation time (battery lifetime)	720 hours	720 hours	Undisclosed on public 510(k) database

[1] Duty cycle for Ivivi was calculated by BioElectronics Corporation, using information available from clinical publications.

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	Undisclosed on public 510(k) database

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 RecoveryRx.

The RecoveryRx 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 RecoveryRx. The skin sensitization test performed in accordance with ISO 10993-10:2010 showed no evidence of an RecoveryRx 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 RecoveryRx 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 RecoveryRx.

The testing that was conducted in accordance with the special controls of the October 13, 2015 Final Reclassification Order demonstrated that the RecoveryRx 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 two randomized, double-blinded, placebo-controlled studies:

- A randomized, controlled, double-blinded study that investigated the effectiveness of RecoveryRx in treating postoperative pain in 18 women who underwent breast augmentation surgery. These women presented with the following average baseline demographics: 31.6 years of age, weight of 134 lbs and height of 5.52 ft. The primary outcome was a difference in daily pain, measured on a 0-10 visual analog pain scale. The results indicate that the effect of active treatment with RecoveryRx provides a statistically significant treatment effect (reduction in postoperative pain), when compared to placebo ($p<0.05$).

- A randomized, controlled, double-blinded study that investigated the effectiveness of RecoveryRx in treating postoperative pain in 96 woman who underwent cesarean section surgery. These women presented with the following average baseline demographics: 27.1 years of age, gestation period of 38.7 weeks and 2 prior cesarean section surgeries. The primary outcome measure was differences in postoperative pain as assessed on a 0-10 visual analog scale. The results indicate that the effect of active treatment with RecoveryRx provides a statistically significant treatment effect (reduction in postoperative pain), when compared to placebo ($p<0.05$).

Conclusion: The non-clinical data and clinical data demonstrate that the RecoveryRx is at least as safe and effective as the predicate devices and can be used as a prescription device for the adjunctive treatment of postoperative pain.