UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

In the Matter of

BIOELECTRONICS CORPORATION,
IBEX, LLC,
ST. JOHN'S, LLC,
ANDREW J. WHELAN,
KELLY A. WHELAN, AND
ROBERT P. BEDWELL,

Respondents.

Administrative Proceeding
File No. 3-17104

RESPONDENTS' MOTION FOR LEAVE TO SUPPLEMENT THE RECORD PURSUANT TO COMMISSION RULES OF PRACTICE 323 AND 452

INTRODUCTION

Pursuant to the U.S. Securities and Exchange Commission's Rules of Practice 323 and 452, Respondents Bioelectronics Corporation ("BioElectronic"), Ibex, LLC, St. John's, LLC, Andrew J. Whelan and Kelly A. Whelan (collectively, "Respondents")[1], respectfully move the Commission for leave to supplemental the record with evidence that is critical to the proper resolution of this matter. Such evidence either became available after the Administrative Law Judge ("ALJ") issued the December 13, 2016 Initial Decision ("Initial Decision"), or the need for which only became apparent after the Initial Decision.

FACTUAL BACKGROUND

In February 2017, approximately two months after the Initial Decision, the Unites States Food & Drug Administration ("FDA") approved BioElectronics' long sought FDA market clearance application to sell its pain products over the counter nationwide. Previously BioElectronics' pain management products could only be sold in Europe or by prescription in the United States (the "FDA Clearance"). Pursuant to Rule 323 Respondents seek judicial notice of the FDA Clearance at **Exhibit 1.**

Respondents also seek judicial notice of the the Internal Revenue Code section 6621(a) and Civil Judgement Code section 228 USC §1961(a) rate tables (the "Interest Rate Tables") Respondent believes such Rate Tables will help the Commission understand certain of its arguments in its opening brief. Copies the Interest Rate Tables are attached hereto **Exhibit 2.**

Finally, pursuant to Rule 452, Respondents seek to have the Declaration of Stanley C. Morris and Brian Flood, that were previously submitted to ALJ Elliot in support of Respondent's Post Hearing Motion to Correct Manifest Errors of Fact In Initial Decision Dated December 13, 2016 (the "Supplemental Evidence"), but it is unclear if those declarations and attachments thereto

[1] All Respondents excluding only Robert P. Bedwell.

were made a part of the formal record. Copies of the Supplemental Evidence are attached hereto at **Exhibit 3.**

ARGUMENT AND AUTHORITIES

A. The Commission Must Take Judicial Notice of the FDA Clearance and Rate Tables Under Rule of Practice 323 Standard for Judicial Notice

Rule of Practice 323 provides that "[o]fficial notice may be taken of any material fact which might be judicially noticed by a district court of the United States, any matter in the public official records of the Commission, or any matter which is peculiarly within the knowledge of the Commission as an expert body."

The FDA Clearance of BioElectronic's products in February 2017, approximately two months after the Initial Decision, is an official, public document that qualifies for judicial notice under this standard. 17 C.F.R. § 201.323.

Similarly, the Internal Revenue Code section 6621(a) and Civil Judgement Code section 228 USC §1961(a) (the "Interest Rate Tables"), are official public documents that qualify for judicial notice under this standard. 17 C.F.R. § 201.323.

B. The Commission Should Grant Leave to Adduce Supplement Evidence Under the Rule 452 Standard.

Rule of Practice 452 provides that "a party may file a motion for leave to adduce additional evidence at any time prior to issuance of decision by the Commission." 17 C.F.R. Respondents must show that the evidence is: (1) material; and (2) there are reasonable grounds for failure to adduce the evidence earlier in the proceeding. *John Thomas Capital Mgmt. Grp. LLC,* Exchange Act Release No. 73819, Commission Order Granting Review and Scheduling Briefs, Dec. 11, 2014.

The Supplemental Evidence easily meets the applicable standard. As to the first prong of the standard, the Supplemental Evidence is not just "material," it is critical to the proper understanding of each sale of IBEX into the securities markets, the time period the security was held prior to sale, and the proceeds from such sale because it contains a declaration and certain calculations performed by an accountant. Furthermore, the Supplement Evidence is also critical for calculating the statute of limitations arguments under 24 U.S.C. 2462 because it contains a declaration of Stanley C. Morris and certain tolling agreements entered between the Division and the Respondents.

As to the second prong, the Supplemental Information was submitted approximately two weeks after the Initial Decision as part of Respondents Post Hearing Motion to Correct Manifest Errors of Fact In Initial Decision Dated December 13, 2016, but it remains unclear if those declarations and attachments thereto were made a part of the formal record. The Respondents only became aware of the significance of the evidence and errors in the Initial Decision after reading the Initial Decision on or about December 13, 2016. The Commission in the Matter of *Ralph W. LeBlanc* permitted the respondent to adduce additional evidence where he was "not aware of the significance" of the evidence "until the law judge's decision issued." Securities Exchange Act Release No. 48254, 2003 WL 21755845, at *6 n.23 (July 30, 2003).

In any event, fairness dictate their inclusion in the record, which Respondent believes will help the Commission understand certain of its arguments in its opening brief which referenced the Supplemental Evidence attached hereto at **Exhibit 3.** For these reasons, the attached exhibits should be considered by the Commission as additional evidence in making its decision.

Dated: Santa Monica, California
March 29, 2017

Respectfully submitted,

CORRIGAN & MORRIS, LLP

By: _____

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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

February 3, 2017

BioElectronics Corporation
Andrew Whelan
President
4539 Metropolitan Court
Frederick, Maryland 21704

Re: K152432
Trade/Device Name: ActiPatch®
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: PQY
Dated: December 2, 2016
Received: December 2, 2016

Dear Mr. Whelan:

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,

Michael J. Hoffmann -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

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)*
K152432

Device Name
ActiPatch®

Indications for Use *(Describe)*
Adjunctive treatment of musculoskeletal pain related to: (1) plantar fasciitis of the heel; and (2) osteoarthritis of the knee

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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"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: ActiPatch 510(k) Summary

1. **Submitter's Name:**
   BioElectronics Corporation
2. **Address:**
   4539 Metropolitan Court
   Frederick, MD 21704
   United States
   Phone: 301-874-4890
   Fax: 301-874-6935

   Contact Person:
   Andrew Whelan
   President and Chief Executive Officer
3. **Date Prepared:**
   December 1, 2016
4. **Trade Name:**
   ActiPatch®
5. **Common Name**
   Non-thermal Shortwave Therapy
6. **Product Classification:**
   21 CFR § 890.5290(b)
   Product code ILX
7. **Predicate Devices:**
   ActiBand (K022404), Ivivi (K070541), Orthocor (K092044)
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 related to: (1) plantar fasciitis of the heel; and (2) osteoarthritis of the knee.

10. Standards:

ISO 13485:2003 Quality System Standard
ISO 13485:2012 Medical Devices: Quality Management Systems
ISO 14155 Clinical investigation of medical devices for human subjects.
ISO 14971: 2012 Risk Management
ISO 10993-6:2009 Part 6 Evaluations of Medical Devices
SOR/ 98-282 G D 207 & GD 210 Canadian MDR Quality Systems
93/42/EEC 2012/47/EC Council Directive
BS EN ISO 15223-1:2012 Labeling of Medical Devices
EN 1041:2008 Information Supplied with Medical Devices
EN 60601-1-2:2012 Electromagnetic Compatibility Requirements & Tests
EN 60601-1-11: 2010 Home Health Care Environment
EN 60601 -1: 2006 Medical Electrical Equipment Requirements and Tests
EN 60601-2-3: 2012 Short-Wave Therapy Equipment
EN 60601-2-10: 2001 Safety of Nerve and Muscle Stimulators
MEDDEV 2.7.1 Rev. 3 Clinical Evaluation
MEDDEV 2.12-1 Rev.8 Vigilance System in Europe
MEDDEV 2.12/2 rev. 2 Post Market Clinical Follow-Up Studies
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 27.12MHz shortwave frequency, pulsing at a 1000 pulses per second with a pulse width of 100µsecs. The duty cycle is therefore 10%. The power source is a 3V battery (CR 2032), producing 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
Antenna size	12cm or 6cm
Treatment area	110cm^2 or 30cm^2
Weight	9.5 grams
Operation time (lifetime of battery)	720 hours
Recommended Treatment Time	Minimum of 12 hours per day

12. Substantial Equivalence:

Substantial Equivalence Comparison Table

	BioElectronics ActiPatch®	**ActiBand (K022404)**	**Ivivi (K070541)**	**Orthocor (K092044)**
Indication for Use	Adjunctive treatment of musculoskeletal pain related to: (1) plantar fasciitis of the heel; and (2) osteoarthritis of the knee	Treatment of edema Following Blepharoplasty	Adjunctive use in the palliative treatment of post-operative pain and edema in superficial soft tissue.	Adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue. Temporary relief of minor muscular and joint aches and pains associated with over-exertion, strains, sprains, and arthritis.
Technology	Pulsed Shortwave Therapy (Non-thermal Diathermy)	Pulsed Shortwave Therapy (Non-thermal Diathermy)	Pulsed Shortwave Therapy (Non-thermal Diathermy)	Pulsed Shortwave Therapy (Non-thermal Diathermy)
Product Code	ILX	ILX	ILX	ILX IMD
Regulation	21 CFR 890.5290(b)	21 CFR 890.5290(b)	21 CFR 890.5290(b)	21 CFR 890.5290(b) 21 CFR 890.5710
Classification Name	Shortwave diathermy	Shortwave diathermy	Shortwave diathermy	Shortwave diathermy
Anatomical sites	Superficial soft tissue	Superficial soft tissue	Superficial soft tissue	Superficial soft tissue
How energy is coupled	Induction coil	Induction coil	Induction coil	Induction coil
Carrier Frequency	27.1 MHz	27.1 MHz	27.1 MHz	27.1 MHz
Pulse duration	100 µsecs	100 µsecs	2 ms	2 ms
Pulse rate	1000 Hz	1000 Hz	2 Hz	2 Hz
Duty cycle	10%	10%	0.4%	0.4%
Power source	3V DC (1 X CR2032 Lithium Battery)	3V DC (Battery)	6V DC (2 X CR2032 Lithium Battery) (or) Mains	3V – 4.2V DC (Battery)
Antenna size (treatment area)	110 cm^2	65 cm^2	285 cm^2	Undisclosed by manufacturer
Averagespatial power density (RMS)	4.4 µWatts/cm^2	4.4 µWatts/cm^2	4.4 µWatts/cm^2	4.4 µWatts/cm^2
Specific absorption rate (W/kg) (Peak)	0.0007 W/kg	0.0007 W/kg	Undisclosed by manufacturer	Undisclosed by manufacturer
Operation time	720 hours	720 hours	Undisclosed by	Undisclosed by

(battery lifetime)			manufacturer	manufacturer
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 by manufacturer	Undisclosed by manufacturer

The table above compares the indication for use and technological characteristics of the ActiPatch with those of the predicate devices.

ActiPatch's technological features are almost 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 ActiPatch. The therapeutic effects of ActiBand® and ActiPatch® are due to the pulsed shortwave signal that is identical between the two devices.

ActiPatch's technological characteristics are also similar to those of the other predicates, for example, ActiPatch has the same carrier frequency as the Ivivi SofPulse device (K070541) and the OrthoCor Knee System (K092044), with only slight technological differences, for example in the pulse duration, pulse rate and duty cycle.

The minor differences in the antenna size between ActiPatch and the predicate devices do 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 ActiPatch compared to the predicates, and that the ActiPatch is at least as safe and effective as the predicates.

ActiPatch has the same intended use as the predicate devices, *i.e.*, the application of electromagnetic energy to non-thermally treat pain. The difference in indications between the predicate products and ActiPatch, including the OTC use, does not result in a new intended use, and the available data on ActiPatch show that it is as safe and effective as the predicates.

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 Non-thermal 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:

a. General Safety and Requirements – Medical Equipment- IEC/EN 60601-1-2:2012

b. General Safety and Requirements – Medical Equipment- IEC 60601-1:2005+A1:2012

c. 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:

Two IRB approved double blind and placebo controlled

randomized controlled trials were conducted in support of this premarket notification. Usability testing was conducted to support the OTC use of the device.

d. The osteoarthritis of the knee study was a double blind randomized controlled study in 66 intent-to-treat patients, out of which 60 patients completed the four-week study. 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. 36% of the treatment group reported a clinically significant decrease in VAS pain, defined as a >30% decrease in pain, compared to 9% for the placebo group, and 18% of the treatment group reported a clinically significant decrease in total WOMAC pain, defined as a >30% decrease in pain, compared to 3% for the placebo group. In the treatment group, 26% stopped pharmacological therapy whereas in the placebo group 33% started a new pharmacological therapy during the study. No adverse events were recorded.

e. The plantar fasciitis study was a double-blind, multicenter, randomized, placebo-controlled study to evaluate the safety and effectiveness of the ActiPatch to reduce the pain level of patients diagnosed with plantar fasciitis. A total of 70 patients completed the study. 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 showed that the average reported pain reduction between the first day's AM pain score and the 7th day's AM pain score for the treatment group was 40% compared to 7% for the control group.

f. Usability testing was conducted on 46 men and women over the age of 17 with a wide range of education levels. These subjects demonstrated use of the ActiPatch on either 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 and clinical data demonstrate that the ActiPatch is at least as safe and effective as its predicate devices, and can be used as an over-the-counter device.