DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 20, 2016

Thimble Bioelectronics, Inc.
Shaun Rahimi
CEO
2011 26th St. Ste. 202
San Francisco, CA 94107

Re: K160052
Trade/Device Name: Cur Model 1
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: April 15, 2016
Received: April 20, 2016

Dear Shaun Rahimi:

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 -A

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)*
K160052

Device Name
CUR Model 1

Indications for Use *(Describe)*
A transcutaneous electrical nerve stimulation (TENS) Mode which is indicated for the symptomatic relief and management of chronic intractable pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. , and

A powered muscle stimulation (PMS) mode which is indicated to improve and facilitate muscle performance in healthy muscles.

The CUR Model 1 should be applied to normal, healthy, dry and clean skin of adult patients.

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.

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510(k) Summary
for
CUR Model 1

This 510(k) Summary has been created per the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR Part 807.92

Submitter Information:

Sponsor Name	Thimble Bioelectronics, Inc.
Contact Person	Shaun Rahimi, CEO
Address	2011 26th St. Ste. 202 San Francisco, CA 94107
Telephone	(408) 799-8783
Fax	-----
Email	shaun@cur.me
Submission Date	January 09, 2016

Device Information:

Device Name	CUR Model 1
Common Name	Transcutaneous Nerve Stimulator
Classification Name	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Classification	Class II 21 CFR 882.5890; 21 CFR 890.5850 Neurology

Predicate Devices

The CUR device is substantially equivalent to the NeuroMetrix ASCEND (K104333) and the Philips Consumer Lifestyle PulseRelief (K151035) devices.

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Device Description

CUR is a high-quality wearable medical device that provides professional-grade TENS therapy along with an easy-to-use interface and compact aesthetic design. It is comprised of the main CUR device, a disposable gel pad, and a charging cable with AC adapter for recharging the device.

A use session typically begins with the user placing the Gel Pad on the skin near the location of pain, attaching the CUR Device to the Gel Pad using the magnetic attachment points on the bottom surface of the Device and on the plastic connector of the Gel Pad. The user then presses the power "start/stop" button on the Device to begin treatment. The user may use buttons on the Device labeled with standard ISO "+" and "-" symbols to control the intensity of treatment. They also may connect the Device to a compatible Mobile Device via Bluetooth and control treatment through the CUR Mobile App. After treatment is finished, the user may leave the Device attached to the Gel Pad until the next treatment session, or may remove the Device from the Gel Pad and attach the Device to the Charging Base using the magnetic attachment points on the Device and Charging Base to store and re-charge the Device.

CUR Model 1 may be used for pain relief on most parts of the body. Intended placements include:

- Shoulder
- Waist
- Back
- Neck
- Upper extremities (arm)
- Lower extremities (leg)

Do not place CUR Model 1 on the throat, chest, or head.

The disposable Gel Pad utilizes a high-quality polyacrylate hydrogel material that provides excellent patient comfort, biocompatibility, and adherence to a wide range of skin types. Pads typically last about 6-10 days with regular daily use and storage before needing to be replaced. And since the Device uses an internal rechargeable battery for power, no other batteries or consumables are needed offering increased convenience and positive benefit to the environment.

The Mobile App provides access to treatment controls and usage instructions for the device from a compatible mobile device. This is an added convenience for cases where the user would rather adjust the treatment from their mobile devices rather than directly from the app and also a means of providing detailed warnings and usage instructions information in a portable way that the user can access at any time.

Indications for Use

A transcutaneous electrical nerve stimulation (TENS) Mode which is indicated for the symptomatic relief and management of chronic intractable pain, and for temporary relief

of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. , and

A powered muscle stimulation (PMS) mode which is indicated to improve and facilitate muscle performance in healthy muscles.

The CUR Model 1 should be applied to normal, healthy, dry and clean skin of adult patients.

Substantial Equivalence

The CUR Model 1 device indications for use and technological characteristics are substantially equivalent to the NeuroMetrix ASCEND device application (K104333) and Philips Consumer Lifestyle PulseRelief device application (K151035).

Comparison Table – Indications for Use

Table 1: Indications for Use Comparison Table

Parameter	Subject Device CUR Model 1	Predicate NeuroMetrix ASCEND (K104333)	Predicate Philips Consumer Lifestyle PulseRelief (K151035)
Indication for Use	A transcutaneous electrical nerve stimulation (TENS) Mode which is indicated for the symptomatic relief and management of chronic intractable pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. , and A powered muscle stimulation (PMS) mode which is indicated to improve and facilitate muscle performance in healthy muscles. The CUR Model 1 should be applied to normal, healthy, dry and clean skin of adult patients.	ASCEND is intended for use as a transcutaneous electrical nerve stimulation device for the symptomatic relief and management of chronic intractable pain. ASCEND is intended for use as a transcutaneous electrical nerve stimulation device for temporary relief of pain associated with sore and aching muscles in the lower extremities due to strain from exercise or normal household and work activities. The device may be used during sleep. The device is labeled for use only with compatible NeuroMetrix electrodes.	The OTC TENS/EMS stimulator PulseRelief is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. It should be applied to normal, healthy, dry and clean skin of adult patients, and is to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.
Class	II	II	II
Product Code	NUH; NGX	NUH	NUH; NGX
Regulation	21 CFR 882.5890(b); 21	21 CFR 882.5890(b)	21 CFR 882.5890(b);

Number	CFR 890.5850		21 CFR 890.5850

Comparison Tables – Technological Characteristics

Basic Unit Characteristics

Table 2: Basic Unit Characteristics Comparison Table

Parameter		Thimble CUR Model 1	Neurometrix Ascend	Philips Pulserelief
510(k) Number		(to be assigned)	K140333	K151035
Device Name and Model Number		CUR Model 1	Ascend	PulseRelief
Manufacturer		Thimble Bioelectronics	NeuroMetrix	Philips Consumer Lifestyle
Power Source(s)		3.7V Lithium-Polymer battery (rechargeable)	3.7V Lithium-ion battery (rechargeable)	3.7V Lithium-ion
Method of Line Current Isolation		Physically isolated; device cannot connect to electrodes and battery recharger concurrently	Physically isolated; device cannot connect to electrodes and battery recharger concurrently	N/A
Patient Leakage Current - Normal Condition (µA)		Battery powered (< 10 µA)	Battery powered (< 10µA)	Battery powered (< 10µA)
Patient Leakage Current - Single Fault Condition (µA)		Battery powered (< 50 µA)	Battery powered (< 100µA)	Battery powered (< 50µA)
Average DC current through electrodes when device is on but no pulses are being applied (µA)		< 0.1µA	< 1µA	0 µA
Number of Output Modes		3 TENS, 1 EMS	1	15 TENS, 5 EMS
Number of Output Channels:	Synchronous or Alternating?	1	1	1
	Method of Channel Isolation	N/A	N/A	N/A
Regulated Current or Regulated Voltage?		Current	Current	Current
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes
Automatic Overload Trip?		Yes	Yes	Yes
Automatic No-Load Trip?		Yes	Yes	Yes
Automatic Shut Off?		Yes	Yes	Yes
User Override Control?		Yes	Yes	Yes
Indicator Display:	On/Off Status?	Yes	Yes	Yes
	Low Battery?	Yes	Yes	Yes (on app)
	Voltage/Current Level?	Yes	No	Yes (on app)
Timer Range (minutes)		60 minutes	60 minutes	1-59 minutes

Parameter	Thimble CUR Model 1	Neurometrix Ascend	Philips Pulserelief
Compliance with Voluntary Standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 10993-5 and -10	IEC 60601-1 IEC 60601-1-2 EN 1497 60601-2-10 ISO 10993-5 and -10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO 10993-5 and -10
Compliance with 21 CFR 898?	N/A	Yes	Yes
Weight (g)	11.5 g	82 g	62 g
Dimensions (mm) (W x H x D)	36 x 36 x 8.5	176 x 63 x 18	2 units, each 54 x 54 x 14
Housing Materials and Construction	Polycarbonate plastic	Plastic, Velcro® straps (Nylon)	PC/ABS plastic

Output Specifications Table for TENS Modes

Table 3: Output Specification for TENS Mode Comparison Table

Parameter		CUR Model 1 Mode A (Default Mode)	CUR Model 1 Mode B	CUR Model 1 Mode C	PulseRelief (K151035)	NeuroMetrix ASCEND (K140333)
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic, Asymmetrical	Biphasic, Symmetrical	Biphasic, Symmetrical	Biphasic, Symmetrical	Biphasic, Symmetrical
Shape (e.g., rectangular, spike)		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (volts) (+/-10%)		42.6V @ 500Ω	43.2V @ 500Ω	42.9V @ 500Ω	31 @500Ω	50V @ 500Ω
		85.2V @ 2kΩ	85.4V @ 2kΩ	86.0V @ 2kΩ	69 @ 2 kΩ	100V @ 2kΩ
		87.0V @ 10kΩ	85.4V @ 10kΩ	87.8V @ 10kΩ	70 @10 kΩ	100V @ 10kΩ
Maximum Output Current (mA) (+/-10%)		85.1 mA @ 500Ω	86.3 mA @ 500Ω	85.6 mA @ 500Ω	62 @500Ω	100mA @ 500Ω
		43.1 mA @ 2kΩ	43.2 mA @ 2kΩ	43.5 mA @ 2kΩ	34 @ 2 kΩ	50mA @ 2kΩ
		8.8 mA @ 10kΩ	8.8 mA @ 10kΩ	8.8 mA @ 10kΩ	7 @10 kΩ	10mA @ 10kΩ
Duration of primary (depolarizing) phase (usec)		91.7 usec	90.5 usec	51.0 usec	25 ~175 µs	100 µs
Pulse Duration (both phases) (usec)		91.7 usec	221 usec	142 usec	60 ~ 350 µs	200µs, additional 30µs inter-phase delay
Frequency (Hz)		40-130 Hz	40-130 Hz	120-160 Hz	1 ~ 100 Hz	Random, mean 80Hz, uniform distribution 60-100Hz
For multiphasic waveforms only:	**Symmetrical phases?**	No	Yes	Yes	Yes	Yes
	Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	91.7 usec (primary phase) 0 usec @ 500Ω (second phase)[1]	90.5 usec	51.0 usec	25 ~ 175 µs	100µs (each phase)

[1] Duration of second phase is load dependent.

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Parameter		CUR Model 1 Mode A (Default Mode)	CUR Model 1 Mode B	CUR Model 1 Mode C	PulseRelief (K151035)	NeuroMetrix ASCEND (K140333)
Net Charge (microcoulombs (µC) per pulse) (If zero, state how this was achieved)		7.16uC @ 500Ω (Nominally 0uC @500Ω per pair of consecutive pulses, zero net current)	Nominally 0uC @ 500Ω, zero net current	Nominally 0uC @ 500Ω, zero net current	0uC @ 500Ω	Nominally 0uC @ 500Ω, zero net current
Maximum Phase Charge, (µC)		7.16 uC @ 500Ω	7.45 uC @ 500Ω	4.14 uC @ 500Ω	1.6 ~ 6.8 uC @ 500Ω	10 µC @ 500Ω
Maximum Current Density, (mA/cm2, r.m.s.)		0.35 mA/cm2 @500Ω	0.50 mA/cm2 @500Ω	0.42 mA/cm2 @500Ω	0.002 ~ 0.045 @500Ω	0.51 mA/cm2 @ 500Ω
Maximum Average Current (average absolute value), mA		0.94 mA @500Ω	1.85 mA @500Ω	1.28 mA @500Ω	0.06 ~1.36 @500Ω	1.6 mA @ 500Ω
Maximum Average Power Density, (W/cm2), (using smallest conductive surface area)		1.50 mW/cm2 @500Ω	3.05 mW/cm2 @500Ω	2.09 mW/cm2 @500Ω	0.24 ~ 1.69 @500Ω	3.6 mW/cm2 @ 500Ω
Burst Mode (i.e., pulse trains):	**(a) Pulses per burst**	N/A	N/A	N/A	5, 7	N/A
	(b) Bursts per second	N/A	N/A	N/A	1,2,3	N/A
	(c) Burst duration (seconds)	N/A	N/A	N/A	62.5 ~ 87.5	N/A
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A	N/A	6.3% ~ 19%	N/A

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Output Specifications Table for PMS Modes

Table 4: Output Specifications for EMS Mode Comparison Table

Parameter		CUR Model 1 (Preset Mode D)	PulseRelief (K151035)
Mode or Program Name		Measured (or Nominal as noted)	from 510k
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic, Symmetrical	Biphasic, Symmetrical
Shape (e.g., rectangular, spike)		Rectangular	Rectangular
Maximum Output Voltage (volts) (+/-10%)		38.4V @ 500Ω	31 @500Ω
		85.0V @ 2kΩ	69 @ 2 kΩ
		85.0V @ 10kΩ	70 @10 kΩ
Maximum Output Current (mA) (+/-10%)		76.7 mA @ 500Ω	62 @500Ω
		43.0 mA @ 2kΩ	34 @ 2 kΩ
		8.1 mA @ 10kΩ	7 @10 kΩ
Duration of primary (depolarizing) phase (usec)		221.5 usec	75 ~175 µs
Pulse Duration (both phases) (usec)		483.8 usec	150 ~ 350 µs
Frequency (Hz)		2-15 Hz	40 ~ 65 Hz
For multiphasic waveforms only:	**Symmetrical phases?**	Yes	Yes
	Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	221.5 usec	75 ~ 175 µs
Net Charge (microcoulombs (µC) per pulse) (If zero, state how this was achieved)		Nominally 0uC @ 500Ω, zero net current	0uC @ 500Ω
Maximum Phase Charge, (µC)		16.21uC @ 500Ω	4.7 ~10.9 uC @ 500Ω
Maximum Current Density, (mA/cm2, r.m.s.)		0.16 mA/cm2 @500Ω	0.0019 ~ 0.037 @500Ω
Maximum Average Current (average absolute value), mA		0.22 mA @500Ω	0.047 ~ 0.93 @ 500Ω
Maximum Average Power Density, (W/cm2), (using smallest conductive surface area)		0.315 mW/cm2 @500Ω	0.62 ~ 1.15 mW/cm2 @500
Burst Mode (i.e., pulse trains):	**(a) Pulses per burst**	N/A	N/A
	(b) Bursts per second	N/A	N/A
	(c) Burst duration (seconds)	N/A	N/A
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A

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Non-Clinical Testing

Non-clinical verification testing of the CUR Model 1 device included electrical, mechanical, and software tests to show the device meets its design specifications. Validation and performance testing validates that the device meets its user needs. Verification and validation test results established that the device meets its intended use, that it is as safe, as effective, and performs as well as the predicate devices, and that no new issues of safety and effectiveness were raised. The CUR device was designed, verified, and validated according to the company's Design Control process and has been subjected to extensive safety and performance testing as shown in the test results provided in this submission. Verification and Validation testing data demonstrate that the device meets all of its specifications including compliance with the following standards:

Safety:

- IEC 60601 1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
- IEC 60601-2-10: 2012 (Second Edition)
- IEC 60601-1-11: 2010 (First Edition):

EMC:

- IEC 60601-1-2:2014
- FCC part 15 RADIO FREQUENCY DEVICES, Subpart B—Unintentional Radiators, Subpart C—Intentional Radiators.

Software:

- IEC 62304:2006

Usability

- IEC 62366-1:2015

Biocompatibility:

- ISO 10993-5:2009
- ISO 10993-10:2010

Clinical Testing

Thimble determined that bench and non-clinical testing were sufficient to demonstrate that the CUR Model 1 device is as safe and effective as the predicate devices.

Conclusion

The intended use and basic technological characteristics of the CUR Model 1 device are substantially equivalent with those of the references predicate devices. Any technological differences do not raise new questions regarding safety and effectiveness. The verification, validation, and performance data presented in this submission demonstrate that the CUR Model 1 device is substantially equivalent to the predicate Ascend and PulseRelief devices.