K121578

JUL 3 1 2012

510(K) Summary

(Per 21 CFR 807.92)

Applicant

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Predicate Device

The BRC 2200 device is substantially equivalent to the transcutaneous electrical nerve stimulator (TENS) device BodiHealth System (K052836).

Device Description

The BRC 2200 is a non-invasive, therapeutic device that delivers bipolar electrical current. In order to maintain a neutral charge for each cycle, the device delivers a current of one polarity for the first half of the cycle and then the opposite polarity for the second half of the cycle.

The BRC 2200 is a hand-held device with a touch screen designed for ease of the user. The licensed healthcare professional uses a pass code to access screens regarding the treatment options and patient information. The main treatment screen shows the progression of the treatment, date, time, battery level, and gives options to pause the treatment or reduce the power if the patient feels discomfort.

The BRC 2200 contains 24 pre-programmed treatments accessible only to the licensed healthcare professional. Using the designated pass code, the licensed healthcare professional selects the treatment and updates the correct patient information to the

device before starting the treatment. Once the treatment has started, the patient will be able to pause the treatment or reduce power if he/she feels mild discomfort.

Components included with the BRC 2200 contain a pair of single-use electrodes, a pair of electrode cables, a battery charger, and an optional USB cable.

The electrodes come in a variety of sizes ranging from extra-small to large and either two inch or three inch widths. The electrodes attach by being circumferentially wrapped around a limb or the trunk of the body and the overlapping ends secured with hook and loop fasteners to maintain circumferential tension during treatment. The electrodes consist of a conductive layer sandwiched between a layer of polyurethane foam and a layer of synthetic neoprene. The foam is in contact with normal, intact skin for up to 3 hours and complies with ISO 10993.

The electrode cables attach to the electrodes via a silver metal hook and loop fastener which then attaches to the BRC 2200 using push-pull connectors. The electrode cables used with the electrodes can be multi-use and are available in 40, 50, and 60 inches in length. These three different sizes in electrode cables allow for differences in the placement of electrodes and the different sizes of patients.

In order to conduct the current through the body, the electrodes require water as the conducting medium. This is achieved by soaking the electrodes in water or normal saline solution and applying to the location in which current flow should be directed.

The BRC 2200 is powered by a Tenergy 3.7V Li-polymer rechargeable battery. The battery is charged by the Tenergy 3.7V Li-ion battery charger model OH-1048A0451500U. The optional USB cable allows the licensed healthcare professional to obtain treatment information and transfer it to a computer.

The BRC 2200 is a prescription device and can be used in a healthcare facility or at home.

Indications for Use

The BRC 2200 is intended for temporary symptomatic relief and management of chronic intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

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Summary of the Technical Characteristics of the BRC2200 as Related to the Predicate Device

Table 1

	Atom 1 (Model: BRC 2200)	BodiHealth
510(k) Number	Pending	K052836
Intended Use	The BRC 2200 is intended for temporary symptomatic relief and management of chronic intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic pain.	The Bodihealth System is intended for temporary symptomatic relief and management of chronic intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic pain.
Power Source	Tenergy Li-ion battery 3.7V – 3Ah	Sealed lead acid rechargeable battery 6V – 4Ah
- Method of Line Current Isolation	N/A	N/A
- Patient Leakage Current	N/A	N/A
- Normal Condition (μA)	N/A	N/A
- Single Fault Condition (μA)	N/A	N/A
Average DC current through electrodes when device is on but no pulses are being applied (μA)	0.002 μA	0.002 μA
Number of Output Modes	24	26
Number of Output Channels	1	1
Regulated Current or Regulated Voltage?	Regulated current	Regulated current
Software/Firmware/Microprocessor Control?	Yes	Yes
Automatic Overload Trip?	Yes	Yes
Automatic No-Load Trip?	No	No
Automatic Shut Off?	Yes	No
Indicator Display: On/Off Status?	Yes	Yes
Indicator Display: Low Battery?	Yes	Yes
Indicator Display: Voltage/Current Level?	Yes	No
Indicator Display: Open Circuit?	Yes	Yes

Timer Range (minutes)	92-161 minutes	User-controlled with 23 minute cycles.
Compliance with Voluntary Standards?	No	No
Compliance with 21 CFR 898?	Yes	Yes
Weight (lbs., oz.)	10.5 oz.	7 lbs., 3 oz.
Dimensions (in.) [W x H x D]	5.9 in. x 3.75 in. x 1.5 in.	9 in. x 4.5 in. x 11 in.
Housing Materials and Construction	Injection-molded plastic case	Injection-molded plastic case
Mode or Program Name	Treatment G, H, or I, Cycle 3	Treatment C
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular
Maximum Output Voltage (volts) (+/- 5%)	1.5V@500 Ω	1.5V@500 Ω
	6V@2 kΩ	6V@2 kΩ
	30V@10kΩ	25V@10kΩ
Maximum Output Current (specify units) (+/- 5%)	3mA@500 Ω	3mA@500 Ω
	3mA@2 kΩ	3mA@2 kΩ
	3mA@10kΩ	2.5mA@ 10 kΩ
Duration of primary (depolarizing) phase (µsec)	N/A	N/A
Pulse duration (µsec)	100 ms	128 ms
Frequency (Hz) [or Rate pps]	10 Hz	7.8 Hz
Net Charge (microcoulombs (µC) per pulse) (If zero, state method of achieving zero net charge)	0 µC @500Ω Symmetrical waveform	0 µC @500Ω Symmetrical waveform
Maximum Phase Charge (µC)	3 µC @500Ω	4.3 µC @500Ω
Maximum Current Density (mA/cm^2, r.m.s.)	0.0205 mA/cm^2@500Ω (3mA/146.577 cm^2)	0.0089 mA/ cm^2@500Ω (3mA/338.7 cm^2)
Maximum Average Current (average absolute value) mA	3mA@500Ω	3mA@500Ω
Maximum Average Power Density (W/cm^2) (using smallest electrode conductive surface area)	30.7µW/ cm^2 @500Ω (0.0045/146.577)	13.297µW/ cm^2 @500Ω (0.0045/338.7)
ON Time (seconds)	9660 seconds (maximum treatment time)	User-controlled
Additional Features (specify, if applicable)	Data-logging	

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Non-Clinical Testing

Testing of the BRC 2200 includes functional performance testing and electrical safety testing in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, and IEC 60601-2-10. Testing of any skin-contacting materials includes biocompatibility testing in accordance with ISO 10993-1, ISO 10993-5, and ISO 10993-10.

Conclusions

In comparison to the BodiHealth System, the BRC 2200 is substantially equivalent and has similar technical, functional, and performance characteristics. The BRC 2200 is designed to comply with the generally accepted performance specifications for TENS devices. The BRC 2200 performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 31 2012

Bioelectric Research Corporation
c/o Ms. Paula Wilkerson
Sr. Staff Engineer, Sr. Reviewer, Program Manager
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Re: K121578
Trade/Device Name: Atom 1, Model BRC 2200
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: July 13, 2012
Received: July 16, 2012

Dear Ms. Wilkerson:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for Jessica Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121578

Device Name: Atom 1

Model: BRC 2200

Indications for Use:

The BRC 2200 is intended for temporary symptomatic relief and management of chronic intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ONTO ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121578