DEC 1 0 2013

510(k) SUMMARY

510(k) Notification K131586

GENERAL INFORMATION

Applicant:

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Palo Alto, CA 94301-1704
U.S.A.
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Contact Person:

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Sunnyvale, CA 94085
U.S.A.
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Date Prepared: December 1, 2013

DEVICE INFORMATION

Trade Name:

Canary Breathing™ System

Generic/Common Name:

Biofeedback device
Carbon dioxide gas analyzer

Classification:

21 CFR§882.5050, Class II
21 CFR§868.1400, Class II

Product Code:

HCC
CCK

510(k) SUMMARY (CONT.)

PREDICATE DEVICES

- InterCure, Inc. RESPeRATE (K020399)
- Respironics Novametrix, LLC, LoFlo C5 CO_2 Sensor (K053174)

INDICATIONS FOR USE

The Canary Breathing™ System is intended for use as a relaxation treatment for the reduction of stress by leading the user through guided and monitored breathing exercises. The device is indicated as an adjunctive treatment of symptoms associated with panic disorder, to be used under the direction of a healthcare professional, together with other pharmacological and/or non-pharmacological interventions.

INTENDED USE

The Canary Breathing™ System ("CBS") is a device used to provide biofeedback based respiratory training to patients with panic disorder. It is intended to train the patient to control their respiratory rate and end-tidal CO_2 levels, which may allow the patient to alleviate abnormal breathing and therefore stress associated with panic attacks.

PRODUCT DESCRIPTION

The CBS is a biofeedback device that provides the user with a series of tone-guided breathing exercises and an awareness of his or her physiological data. The CBS uses standard biofeedback concepts to teach the patient to regulate their end-tidal CO_2 ($EtCO_2$) and respiratory rate (RR). The user's physiological data display allows the patient to see 1) the actual rate of their breathing and 2) how changes in breathing mechanics (depth and volume) affect $EtCO_2$ levels. The CBS consists of a biofeedback training software program (mobile app) and an $EtCO_2$ sensor (capnometer) used with a nasal cannula. The mobile app guides the user through an exercise and displays physiological data, while the sensor collects physiological data and feeds it to the mobile application for biofeedback. The patient's $EtCO_2$ levels and RR are relayed from the capnometer to the mobile application via Bluetooth and are displayed on a tablet device, through the mobile application.

SUBSTANTIAL EQUIVALENCE

The technological characteristics and intended use of the CBS are substantially similar to an existing biofeedback device, the InterCure, Inc. RESPeRATE. The RESPeRATE trains the patient to synchronize his or her breathing to the guiding tones and biofeedback displays on the device. The RESPeRATE gradually prolongs the exhalation tone to slow down breathing as an adjunctive treatment for high blood pressure, with other pharmacological and/or non-pharmacological interventions. The difference in the specific intended use (reduction in blood pressure vs. reduction in symptoms of panic disorder) does not raise new issues of safety and effectiveness as in both cases the devices use normalized breathing to help alleviate an abnormal condition caused in part by stress and in both cases the biofeedback device is used as an adjunct to other pharmacological and/or non-pharmacological interventions.

510(k) SUMMARY (CONT.)

Both the CBS and the RESPeRATE provide a respiratory training protocol that uses biofeedback for relaxation (reduction of stress), and both devices are intended as adjunctive devices to other forms of pharmacological and/or non-pharmacological therapy. Both devices include a computerized control unit and a sensor. The RESPeRATE sensor is a band that goes around the patient's upper abdomen to measure breathing rate and depth. The CBS uses a capnometer to measure breathing rate and $EtCO_2$.

The capnometer is substantially equivalent to an existing portable capnometer (LoFlo C5 CO_2 capnometer manufactured by Respironics Novametrix, LLC) as determined by bench testing. The LoFlo C5 CO2 capnometer, per the predicate IFU, is used to monitor carbon dioxide in recovery and emergency medicine or respiratory care. Its use in measuring carbon dioxide and respiratory rate in the CBS system for the adjunctive treatment of panic attacks does not raise new issues of safety and effectiveness. Thus, the CBS is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary non-clinical and clinical testing was conducted to support a determination of substantial equivalence to the predicate devices.

NON-CLINICAL DATA

The following table lists the non-clinical testing performed and the results for each test.

Testing Type	Test Description	Result
CBS Design Verification	Canary CO_2 Sensor Functional Testing	The CBS passed all functional testing and met all product specification requirements.
	Canary CO_2 Cannula Functional Testing	
	Nexus 7 tablet Functional Testing	
	Canary Mobile Application Functional Testing	
CBS Integration Testing	The integration testing assessed the integrity of RS232 serial output data generated by an OEM purchased Respironics LoFlo capnometer module integrated into a Canary Breathing System (CBS) capnometer.	RR, $ETCO_2$ and error information were successfully and accurately transmitted to the Nexus tablet running the CBS software.
Software Verification and Validation	Canary CO_2 Sensor Software Testing (The Level of Concern for the CBS software was determined to be "Minor".)	The Canary CO_2 Sensor Software met all requirements of the SRS.
Capnometer Equivalency Verification	Canary CO_2 Sensor Accuracy Testing	The performance of the Canary CO_2 Sensor is equivalent to theLoFlo predicate device, for $EtCO_2$ and respiratory rate measurements.
Electrical Safety and Electromagnetic Compatibility	Testing in accordance with the following standards: • IEC 60601-1:1988 • IEC 60601-1-2:2007 • IEC 60601-1-4:2000 • IEC 60601-1-11:2010	The CBS met all acceptance criteria in accordance with: • IEC 60601-1:1988 • IEC 60601-1-2:2007 • IEC 60601-1-4:2000 • IEC 60601-1-11:2010

CLINICAL DATA

The CBS is based on the capnometry-assisted respiratory training (CART) protocol developed by Alicia Meuret, Ph.D., a clinical psychologist and Associate Professor in the Department of Psychology at Southern Methodist University (Dallas, Texas) in collaboration with colleagues at Stanford University, Boston University and Southern Methodist University. Dr. Meuret and colleagues have published three peer reviewed articles describing the results of two randomized clinical trials using the CART protocol to treat patients with panic disorder. The references are listed below. Findings of these empirical studies have shown that completing the CART training led to long-lasting

reductions in panic attack frequency and severity, anxiety symptoms, avoidance behaviors, along with improvements in mood and quality of life in the majority of patients. Respiratory training using the CART protocol is safe, and no adverse events associated with the use of the device have been reported. Causal analysis linked the normalization in CO_2 to the observed improvements.

The CBS and CART protocol lead the user through identical exercises, however, the user interface for the CBS device is different from that used in the CART protocol studies. The CBS uses a tablet based mobile application, in place of the tape recorder used in the CART protocol. Both devices use a capnometer to measure $EtCO_2$ levels and respiratory rate and to provide the patient with feedback on these parameters. Therefore, the clinical results obtained by following the CART protocol in the above mentioned studies can be directly applied to the CBS device.

Clinical Study References:

Meuret AE, et al. Feedback of end-tidal pCO_2 as a therapeutic approach for panic disorder. *Journal of Psychiatric Research* 2008;42;560-8.

Meuret AE, et al. Changes in respiration mediate changes in fear of bodily sensations in panic disorder. *Journal of Psychiatric Research* 2009;43;634-41.

Meuret AE, et al. Respiratory and Cognitive Mediators of Treatment Change in Panic Disorder: Evidence for Intervention Specificity. *Journal of Consulting and Clinical Psychology* 2010;78;691-704.

The collective performance testing demonstrates that the CBS does not raise new questions of safety or effectiveness when compared to the predicate devices. The results of the performance testing demonstrate that the CBS performs as intended and that its biofeedback protocol is safe and effective for reducing symptoms associated with panic disorder.

CONCLUSION

The CBS has the same intended use and similar technological characteristics as the predicate biofeedback devices as well as the same physiological parameter measurements as the predicate capnometer. The differences in the means for collecting physiological data for biofeedback does not change the intended use or raise any new issues of safety or effectiveness as compared to the predicate biofeedback devices.

SUMMARY

The CBS is substantially equivalent to the predicate devices.

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

December 10, 2013

Palo Alto Health Sciences, Inc.
c/o Dr. Lori Adels
Regulatory Consultant
755 N Mathilda Ave., Suite 100
Sunnyvale, CA 94085

Re: K131586
Trade/Device Name: Canary Breathing System
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: HCC and CCK
Dated: November 1, 2013
Received: November 4, 2013

Dear Dr. Adels:

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 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. 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,

Victor Krauthamer -A

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131586

Device Name: Canary Breathing System

Indications For Use:

The Canary Breathing System is intended for use as a relaxation treatment for the reduction of stress by leading the user through guided and monitored breathing exercises. The device is indicated as an adjunctive treatment of symptoms associated with panic disorder, to be used under the direction of a healthcare professional, together with other pharmacological and/or non-pharmacological interventions.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Victor Krauthamer -A
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