August 23, 2018

Palo Alto Health Sciences, Inc.
% Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2834 Hawthorn St.
San Diego, California 92104

Re: K180173
Trade/Device Name: Freespira
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: HCC, CCK
Dated: July 23, 2018
Received: July 24, 2018

Dear Allison Komiyama:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela D. Scott -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)*
K180173

Device Name
Freespira

Indications for Use *(Describe)*
Freespira 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 (PD) and/or posttraumatic stress disorder (PTSD), to be used under the direction of a healthcare professional, together with other pharmacological and/or non-pharmacological interventions.

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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510(k) Summary
K180173

DATE PREPARED
August 23, 2018

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
Freespira®

COMMON NAME / DEVICE CLASSIFICATION
Device, Biofeedback (21 CFR 882.5050, HCC, Class II)
Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase (21 CFR 868.1400, CCK, Class II)

PREMARKET REVIEW
ODE/DNPMD/Neurodiagnostic and Neurosurgical Devices Branch (NDNB)
ODE/DAGRID/Anesthesiology Devices Branch (ANDB)

INDICATIONS FOR USE
Freespira® 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 (PD) and/or posttraumatic stress disorder (PTSD), to be used under the direction of a healthcare professional, together with other pharmacological and/or non-pharmacological interventions.

510(k) Summary

DEVICE DESCRIPTION

Freespira® 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 (PD) and/or posttraumatic stress disorder (PTSD), to be used under the direction of a healthcare professional, together with other pharmacological and/or nonpharmacological interventions. Freespira is authorized and overseen by a licensed healthcare provider. Patients are trained to use the Freespira Sensor and the Freespira Mobile App to measure and display their exhaled carbon dioxide ($EtCO_2$) level and respiration rate (RR) and how different breathing habits affect $EtCO_2$ levels.

PREDICATE DEVICE IDENTIFICATION

Freespira is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K131586	Canary Breathing™ System	Yes

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for Freespira. Reports on the following tests were provided to demonstrate safety based on current industry standards:

Biocompatibility: Patient contacting material was evaluated for biocompatibility in compliance to ISO 10993-1:2009(R)2013 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.

Software Verification: The software development and testing was executed according to FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Electromagnetic Compatibility and Electrical Safety: The subject device was tested in compliance to methods outlined in IEC 60601-1:1988 +A1:1991 +A2:1995 - *Medical Electrical Equipment Part 1: General Requirements for Safety*; ANSI/AAMI ES60601-1:2005 *Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance*; IEC/EN 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*; IEC 60601-1-4:1996 + A1:1999 - *Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems*; and IEC 60601-1-11:2010 - *Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*

SUMMARY OF CLINICAL TESTING

Palo Alto Health Sciences Inc. performed a prospective, single arm, un-blinded investigation of Freespira in the indicated population. Patients with a primary diagnosis of PTSD (military and non-military, combat and non-combat) were enrolled into a four-week Freespira program. At enrollment, and then at specified intervals, patients underwent assessment using validated questionnaires (PHQ-9, SF-36, PDSS, CGC-S and CAPS-5 30-day score). In addition, every time a patient used Freespira, their EtCO2 and RR data were stored locally (on the tablet) and securely uploaded to a cloud server for clinician review.

The primary endpoint of this study was: quantitative improvements using the Clinician Administered PTSD Scale (CAPS-5). Using this scale, "Response" was defined as a reduction of 6 or more points. "Remission" was defined as Response plus no longer meeting clinical symptom criteria and having a severity score < 25.

The primary effectiveness hypothesis was that from baseline to the 2-month follow-up, at least 50% of study participants will experience a response to the treatment (defined as a 6-point reduction in CAPS-5 score from baseline).

Results demonstrate that this hypothesis was met: at 2-month post-treatment follow-up, the proportion of responders was 93% [with 95% CI between 77-99%]. In addition, at 2-months the rate of remission was 48% and the mean CAPS score decreased from 52.0 at baseline to 25.8.

Post-treatment (week 5) the proportion of responders was 88% [with an unadjusted 95% CI between 71-96%] and the rate of remission was 25%. Mean CAPS score decreased from 52.0 at baseline to 32.0.

At the 6-months post-treatment follow-up, the proportion of responders was 91% [with an unadjusted 95% CI between 71-99%] and the rate of remission was 50%. The mean CAPS-5 score decreased from 52.0 at baseline to 27.0 showing stability of improvement.

A consistently large proportion of subjects achieved a decrease in their CAPS-5 score as the threshold definition of response increased in magnitude (from 11% to 40% of the change from baseline).

Response Rates with increasing Thresholds of Response Definition

	>=6 pts decrease from baseline [=11%]*	**>=10 pts decrease from baseline [=19%]***	**>=13 pts decrease from baseline [=25%]***	**>=16 pts decrease from baseline [=30%]***	**>=21 pts decrease from baseline [=40%]***
Post-tx	88%	81%	71%	59%	38%
2-months	93%	83%	84%	69%	59%
6-months	90%	86%	86%	73%	59%

*% change from mean baseline score of 52.0

The following adverse events were reported as possibly related to the treatment: chest pain, cold symptoms, and headache.

Patient satisfaction with Freespira was high post-treatment (84%), at 2-months (74%), and 6-months (90%) post-treatment. These percentages were based on the number of patients who gave a score of 3 or 4 on a 0-4 scale (where “0” meant “not satisfied” and “4” meant “very satisfied”) at each time point.

The clinical data demonstrate that Freespira provides a safe and effective, adjunct at-home treatment for the symptoms associated with PTSD that can be easily and widely disseminated. Freespira is completed in 4-weeks at-home without unpleasant side-effects. This likely contributed to the relatively low dropout rate (20%), high protocol adherence (77%), and high satisfaction scores (84%).

EQUIVALENCE TO PREDICATE DEVICE

Freespira is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same design and dimensions, and uses identical materials as the device cleared in K131586. The subject device has the same technological characteristics to the device cleared in K131586 except that the device can now also be used while it is plugged into the AC power adaptor. The fundamental difference between the two devices is that the subject device has expanded indications that include its use as an adjunct treatment for symptoms associated with PTSD. The subject device has undergone bench and clinical testing to ensure the device is as safe and effective as the predicate.

CONCLUSION

Based on the testing performed, namely a prospective clinical study, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate device. The similar technological characteristics and performance characteristics for the proposed Freespira are assessed to be substantially equivalent to the predicate device. The device is considered safe and effective for its intended use.