August 1, 2024

DeepWell DTx Inc.
Caitlyn Dzhafarov
Regulatory Affairs Consultant, Medical Devices Pathway, LLC
5608 17 Ave NW Suite 570
Seattle, Washington 98107

Re: K233580
Trade/Device Name: A Breathing System (ABS)
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: HCC
Dated: July 3, 2024
Received: July 3, 2024

Dear Caitlyn Dzhafarov:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Kang -S

for Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233580

Device Name

A Breathing System (ABS)

Indications for Use *(Describe)*

A Breathing System (ABS) is intended for use as a relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure, 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.

510(k) #: K233580

510(k) Summary

Prepared on: 2024-07-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DeepWell DTx Inc.
Applicant Address	5608 17 Ave NW Suite 570 Seattle WA 98107 United States
Applicant Contact Telephone	250-516-7826
Applicant Contact	Mr. Harris Jeff
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Correspondent Address	14330 178th Ln NE Woodinville WA 98072 United States
Correspondent Contact Telephone	360-224-3622
Correspondent Contact	Ms. Caitlyn Dzhafarov
Correspondent Contact Email	cdzhafarov@meddevpath.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	A Breathing System (ABS)
Common Name	Biofeedback device
Classification Name	Biofeedback device
Regulation Number	882.5050
Product Code	HCC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K020399	RESPeRATE	HCC

Device Description Summary

21 CFR 807.92(a)(4)

A Breathing System (ABS) is a software development kit (SDK) designed to provide Android app developers a reliable biofeedback mechanism to induce relaxation and address some symptoms of mild to moderate stress and anxiety. ABS SDK operates on Android devices capable of supporting Android 6.0 'Marshmallow' or newer operating systems. The ABS utilizes the integrated microphone or optionally the integrated accelerometer of a mobile device to detect and monitor breath rate during breath guided breathing exercises. Notable device features include a user-friendly interface for guided breathing, synchronization of breath and tracking of breath rate. The system also provides a mechanism for recovery if synchronization is lost. For best results users engage in 15-minute sessions for at least 45 minutes per week.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

A Breathing System (ABS) is intended for use as a relaxation treatment for the reduction of stress by leading the user through

interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure, together with other pharmacological and/or non-pharmacological interventions.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use and indications for use between the ABS (A Breathing System) and the RESPeRATE are identical. The ABS device is not proposing any modifications from the intended use or indications for use statement cleared by its selected predicate, RESPeRATE.

Technological Comparison

21 CFR 807.92(a)(6)

The mechanism of action leading to the therapeutic effect between the subject and predicate device is the same, guided breathing at 10 breaths or less per minute for a 15-minute treatment duration. As well, both devices are offered as an OTC device. ABS additionally offers an optional use of breath detection through microphone, which was tested and found to be equivalent through usability and functional device testing.

The ABS alternatively utilizes some different technological characteristics outside the biofeedback mechanism. Primarily the use environment is different; the ABS, as an android based SDK exhibits adaptability, functioning on various mobile platforms that support Android 6.0 or higher operating systems, offering versatile deployment options. In contrast, the RESPeRATE is a dedicated, self-contained device.

With regard to user interface and control mechanisms, there are minor differences between the two devices that do not impact the intended use or fundamental technology. These different experiences are predicated in the platform's design and technological capabilities.

ABS, if not preloaded on a mobile device, requires internet connectivity for specific features, such as downloading the application and receiving updates, in contrast, RESPeRATE operates independently on a non-connected device.

Any technological differences do not impact the therapeutic effect demonstrated by the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Text box equivalence

The ABS test planning included bench top verification of the ABS's equivalence to the predicate device as well as testing to support each user need, design input and design output.

Usability testing per the ABS Usability Testing protocol was conducted with 21 users. The test confirmed over 85% of the users were able to easily utilize the ABS device in either (microphone or accelerometer) detection mode. Users easily detect and sync their breath to the target breath rate. Test Report: (DOC:383)

The ABS represents a lower cost, higher accessibility alternative to the predicate and
has been found, Per the Risk Assessment and the risk acceptability criteria defined in the ABS Risk Management Plan(DOC 441) to be low risk and raised no new levels of concern that were not adequately addressed in the design and development process.

Not Applicable

Bench testing has been used to confirm the design inputs have been satisfied by the design outputs for A Breathing System (ABS) periodically throughout the development cycle. Protocols are written and released in the Deepwell DTx quality system. All executed protocols should carry the release information on the last page of the document and become the data capture document.

User needs, Design Inputs, Design Outputs, Verifications and Validations are traced in DeepWell Quality System under PDPROJ-2 ABS to aid in complete visibility to testing needs.

The latest verification testing of the Unity based version was conducted on November 1, 2023, per ABS Unity version general function verification rev A and ABS mobile phone (unity) version user messaging verification rev B reported in ABS Unity version software verification test report rev A (DOC#404). Messages as well as functional elements were tested. This report concludes that ABS Unity version 0.09 functions as intended and meets the design inputs as required.

The latest verification testing was conducted on August 14, 2023, on the Mobile VR (Unreal) version of ABS as incorporated in FLOJO. The testing consisted of executing ABS Test Protocol breath target rate and detection rev B, SLOJO Test Protocol breath target rate and system clock rev A, and FLOJO SLOJO ABS Test Protocol user messaging verification rev B and reported in the ABS Software Verification / Validation test report rev E(DOC#330). All functional testing and messaging conformed to the design inputs as required.

A side-by-side comparison of ABS Unity version and a RESPeRATE device was conducted per the ABS RESPeRATE comparative testing protocol rev A on November 2, 2023, as reported in the ABS Unity RESPeRATE comparative test report (DOC#411). This report shows that the breathing rate detection methods for ABS and the RESPeRATE unit deliver the same results within the measurement error using a stopwatch to measure a five-minute interval.

ABS Usability Test Results (DOC#383)
85% of Users Successfully Matched Target Breath Rate with Microphone Input.
89% of Users Successfully Matched Target Breath Rate with Accelerometer Input.
This protocol has verified that usability meets the design input requirements. ABS is incorporated in APPs or games as the therapy mode, section or mechanic and was tested in fore usability in the Game / App environment.

Predicate/Reference Substantial Equivalence Basis Summary

Product Characteristics	**DeepWell ABS** ***Subject Device***	**Intercure RESPeRATE** **K020399** ***Predicate Device***	**SE Comparison**
Common name	Biofeedback Device	Biofeedback Device	Same
Device Manufacturer	DeepWell DTx	No. 2breathe Technologies	N/A
Device Class	II	II	Same
Primary product code	HCC	HCC	Same
Target Population	People who suffer or have suffered in the past with these conditions should first consult their physician: Active ischemic heart disease/unstable angina, bradycardia, severe congestive heart failure, chronic atrial fibrillation, stroke resulting in permanent impairment, chronic renal failure, severe asthma, chronic obstructive pulmonary disease (COPD), chronic bronchitis and emphysema, major organ failure, sleep paralysis, have a pacemaker, or if you are pregnant.	People who suffer or have suffered in the past with these conditions should first consult their physician: Active ischemic heart disease/unstable angina, bradycardia, severe congestive heart failure, chronic atrial fibrillation, stroke resulting in permanent impairment, chronic renal failure, severe asthma, chronic obstructive pulmonary disease (COPD), chronic bronchitis and emphysema, major organ failure, sleep paralysis, have a pacemaker, or if you are pregnant.	Same

Environment	Sitting. Used anywhere that is relatively quiet, and considered a safe environment where the individual can concentrate on the therapy without distraction. Do not use when you need to be alert or to concentrate or when using heavy equipment. Do not use while driving.	Sitting. Used anywhere except in water. Do not use when you need to be alert or to concentrate or when using heavy equipment. Do not use while driving.	Same
Intended Use	A Breathing System (ABS) is intended for use as a relaxation treatment by leading the user through interactively guided and monitored breathing exercises. OTC	The RESPeRATE is intended for use as a relaxation treatment by leading the user through interactively guided and monitored breathing exercises. OTC	Same
Indications for Use	The ABS device is indicated for the reduction of stress, and for use only as an adjunctive treatment for high blood pressure, together with other pharmacological and/or non-pharmacological interventions.	The device is indicated for the reduction of stress, and for use only as an adjunctive treatment for high blood pressure, together with other pharmacological and/or non-pharmacological interventions.	Same
Parameters Monitored	Breathing rate	Breathing rate	Same
Alarms	No	No	Same
Energy Source	Supplied by the third-party compatible device the SDK is running on.	Batteries	Equivalent

Interfaces	The device itself does not have a hardware UI; the software UI is displayed on the host device.	LCD Screen	Equivalent
Displayed Information on Interface	The platforms interfaces for the ABS contain session time, breaths per minute, a timer for therapeutic minutes, a visual indicator to guide through breathing exercises, visual cue when synched breathing is achieved, on-screen instructions, particles that change color depending on if the user is breathing properly or not (green is in sync and red means out of sync)	Displays - User 1, User 2, Low Battery, Guiding Figure, Breath Gauge, Therapeutic Minutes Clock, Sensor Belt Error, Volume, Info Function, Tutorial On, Session Duration, Performance Report Period, Breaths per Minute, Session Duration, Voice Instructions on/off, Melody selection.	Equivalent (*though the devices display information unique to their respective designs, both are equivalently designed to provide the user with the information necessary to properly use the device*) both provide visual and auditory cues to p
Method of Monitoring Breath Rate	Accelerometer & Auditory Inputs (Microphone)	Accelerometer	Accelerometer: Similar Auditory Inputs: found to be equivalent method of detecting breath through testing.
Site of Breath Rate Monitoring	Microphone, and optionally upper/lower sensor (accelerometer) to computerized main unit.	Upper/lower sensor (accelerometer) to computerized main unit	Equivalent (*Both devices primarily monitor respiration rate by analyzing breathing patterns.* *The predicate RESPeRATE achieves this by utilizing a sensor belt positioned around the upper abdomen as an accelerometer for monitoring breathing.*

			The subject ABS offers flexibility by utilizing the operating device itself or optionally a sensor placed on the upper abdomen, similar to the predicate RESPeRATE sensor belt. Both of the ABS's approaches provide accurate measurements and user feedback. Tested to work equivalently to the predicate device.
Resolution	Displays capable of rendering 16-bit color graphics. Technology used MUST have a pixel aspect ratio (PAR) between 0.9 and 1.15.	LCD	Similar
Mechanism of Action	Controlled Breathing 10 or less breaths per minute	Controlled Breathing 10 or less breaths per minute	Same
Duration of Treatment	15 minutes	15 minutes	Same
Principle of Operation	Guided Breathing technology	Guided Breathing technology	Same
Frequency of Treatment	15 minutes per session at least 45 minutes per week.	45 minutes a week, 3 sessions a week preferred.	Same
Hardware Requirements/Device Compatibility	**Minimum Hardware:** - **Display:**	RESPeRATE Device, display and accelerometer with optional headphones.	Similar

	MUST support displays capable of rendering 16-bit color graphics. Technology used MUST have a pixel aspect ratio (PAR) between 0.9 and 1.15. - **Microphone**: MUST allow capture of raw audio content with the following characteristics: • Format: Linear PCM, 16-bit • Sampling rates: 8000, 11025, 16000, 44100 • Channels: Mono - **Accelerometer:** MUST have a resolution of at least 12-bits, standard deviation no greater than 0.05 m/s^, where the standard deviation should be calculated on a per axis basis on samples collected over a period of at least 3 seconds at the fastest sampling rate.		
Output Measurement	**Time**	Time	Same