July 5, 2022

ResApp Health
Neroli Anderson
VP Clinical, Quality And Regulatory
Level 12, 100 Creek Street
Brisbane, Queensland 4000
Australia

Re: K213360
Trade/Device Name: SleepCheckRx
Regulation Number: 21 CFR 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: Class II
Product Code: MNR
Dated: June 9, 2022
Received: June 10, 2022

Dear Neroli Anderson:

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/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 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 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,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213360

Device Name
SleepCheckRx

Indications for Use *(Describe)*
SleepCheckRx is indicated to record a patient's respiratory pattern during sleep for the purpose of pre-screening patients for obstructive sleep apnea (OSA) syndrome.
The device is designed for use in home-screening of adults (≥ 22 years of age) with suspected possible sleep breathing disorders. Results can be used to assist the healthcare professional in determining the need for further diagnosis and evaluation.
The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements, or EEG activity are required.

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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K213360 510(k) Summary

(As required by section 807.92(c))

SLEEPCHECKRx

I. GENERAL INFORMATION

Submitter:
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Date Prepared: July 02, 2022

II. DEVICE DETAILS

Trade Name:	SleepCheckRx
Common or Usual Name:	Breathing Frequency Monitor
Classification Name:	Device: Ventilatory Effort Recorder
Regulation:	21 CFR 868.2375
Regulatory Class:	II
Product Code:	MNR
Review Panel:	Anesthesiology

III. PREDICATE DEVICE

Predicate Device(s): DROWZLE (K173974)

IV. DEVICE DESCRIPTION

SleepCheckRx is a software application used by healthcare providers to pre-screen adults at home for the risk of Obstructive Sleep Apnea (OSA). The application is accessed via a compatible smartphone and uses the device's inbuilt microphone to record breathing and snore sounds while the user is asleep, over a minimum duration of 6 hours.

This audio recording, in conjunction with basic information about the user, is analyzed by locked machine learnt software algorithms to provide a risk assessment of the presence of OSA. Prior to use, the patient installs SleepCheckRx on a compatible smartphone and activates the application by entering a code issued to their Healthcare Professional (HCP) through a secure cloud server portal.

The patient enters basic information including date of birth, biological sex, height, weight, and neck circumference. The patient is also required to answer a STOP-Bang questionnaire. The phone is placed on a nightstand as directed, and when the user is ready to go to sleep, they initiate the software that begins a recording.

SleepCheckRx then captures breathing and snore sounds continuously throughout the night until the user stops the recording once they have awoken in the morning (a minimum of 6 hours of recording is required).

In the event of a successful recording, SleepCheckRx provides the user with a binary outcome of either 'Minimal to Mild Risk of OSA' (AHI<15) or 'Moderate to Severe Risk of OSA' (AHI ≥15).

SleepCheckRx requires a healthcare professional (HCP) to access a secure cloud server portal to provide the patient with an access code to use the app downloaded from the Apple App Store.

The results of the patient's recording and the STOP-Bang questionnaire are shared with the patient and the HCP, for the HCP to then determine if further investigation and evaluation is required.

V. INDICATIONS FOR USE

SleepCheckRx is indicated to record a patient's respiratory pattern during sleep for the purpose of pre-screening patients for obstructive sleep apnea (OSA) syndrome.

The device is designed for use in home-screening of adults (≥ 22 years of age) with suspected possible sleep breathing disorders. Results can be used to assist the healthcare professional in determining the need for further diagnosis and evaluation.

The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements, or EEG activity are required.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary comparison of technological characteristics between the SleepCheckRx and the predicate device is provided below.

Device Name	DROWZLE	SleepCheckRx	Comparison
510k number	K173974	K213360	N/A
Regulation Number	21 CFR§ 868.2375	21 CFR§ 868.2375	Same regulation number.
Regulation Name	Breathing Frequency Monitor	Breathing Frequency Monitor	Same regulation name.
Product Code	MNR	MNR	Same product code.
Intended Use	Home-use for screening patients with possible sleep disorders.	Home-use for screening patients with possible sleep disorders.	Equivalent. Both devices intended to home screen patients with possible sleep disorders.
Indications for Use	DROWZLE is indicated to record a patient's respiratory pattern during sleep for the purpose of prescreening patients for obstructive sleep apnea (OSA) syndrome. The device is designed for use in home-screening of adults with suspected possible sleep breathing disorders. Results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation. The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements, or EEG activity are required.	SleepCheckRx is indicated to record a patient's respiratory pattern during sleep for the purpose of pre-screening patients for obstructive sleep apnea (OSA) syndrome. The device is designed for use in home-screening of adults (≥ 22 years of age) with suspected possible sleep breathing disorders. Results can be used to assist the healthcare professional in determining the need for further diagnosis and evaluation. The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements, or EEG activity are required.	Equivalent indications for use. Both devices intended to record a patient's respiratory pattern during sleep for the purpose of pre-screening patients for obstructive sleep apnea (OSA) syndrome.
Target Population	Adults	Adults	Equivalent. Both devices intended for use on adults.
Intended Use Environment	Home Environment	Home Environment	Equivalent. Both devices intended for the home environment

Device Name	DROWZLE	SleepCheckRx	Comparison
Type of Use	Prescription Use (Part 21 CFR 801 Subpart D)	Prescription Use (Part 21 CFR 801 Subpart D)	Both devices are prescription only use.
Method of Measurement	Acoustic analysis of breathing and snoring sounds.	Acoustic analysis of breathing and snoring sounds.	Equivalent. Both devices analyze breathing and snoring sounds.
Mode of Action	Analyses breathing sounds to identify respiratory events indicative of OSA or other disorders.	Analyses breathing sounds to identify respiratory events indicative of OSA or other disorders.	Equivalent. Both devices identify respiratory events indicative of OSA or other disorders.
Sensor Placement Site	Smartphone placed within 24 inches of pillow.	Smartphone placed next to the bedside (on a nightstand).	Equivalent. Both devices utilize smart phones placed in close proximity while sleeping.
Sensor Elements	Microphone(s) native to smartphone.	Microphone(s) native to smartphone.	Equivalent. Both devices utilize microphone(s) native to the smartphone.
Patient Contact	Software only. No direct patient contact.	Software only. No direct patient contact.	Equivalent. Software only. Neither device patient contacting.
Portability	Yes	Yes	Equivalent. Both devices downloaded onto a smartphone.
Measured Variable	Oral and nasal breath sounds.	Oral and nasal breath sounds.	Equivalent. Both devices detect oral and nasal breath sounds.
Breathing Events	Breath sound gaps >10 seconds.	Breathing pauses of duration ≥ 6s but < 60 seconds.	Equivalent. Both devices detect beathing events (however the algorithms have been trained to detect events of different durations).
Sensor Attachment	N/A	N/A	Equivalent. Neither device has a sensor attachment.
Display Type	Smartphone display	Smartphone display	Equivalent. Both devices utilize the smartphone display.
Signal Loss Indicator	N/A	N/A	Equivalent. Neither device has a signal loss indicator.
Reported Metrics	Risk of OSA based on the following AHI estimates:	Risk of OSA based on the following AHI estimates:	Equivalent. Both devices report the risk

Device Name	DROWZLE	SleepCheckRx	Comparison
	• Minimal to Mild Risk of OSA (AHI<15) • Moderate to Severe Risk of OSA (AHI ≥15). Risk classification based on standard questionnaires: a. STOP-Bang b. Epworth Sleepiness Scale c. Calculated Resonea Index	• Minimal to Mild Risk of OSA (AHI<15) • Moderate to Severe Risk of OSA (AHI ≥15). STOP-Bang questionnaire is also reported.	of OSA based on a binary output, i.e., either minimal to mild risk of OSA (AHI<15), or moderate to severe risk of OSA (AHI ≥15). Both devices report the STOP-Bang score. SleepCheckRx does not report the Epworth scale, nor does it display a proprietary index score.
Reporting of Results to HCP	Results are available for review by the clinician via email.	Results are available for review by the clinician via the portal.	Equivalent. Both devices may be reviewed via a clinician portal.
Sleep Night Use	Can be used multiple nights.	Can be used multiple nights.	Equivalent. Both devices may be used over multiple nights.
Maximum Run-time	No maximum run-time.	No maximum run-time.	Equivalent. Neither device specifies a maximum run-time.
Minimum Time Required for result	2 hours	6 hours	SleepCheckRx is required to be used for a longer period of time (6 hours) to ensure more accurate results.
Controller	Smartphone microprocessor.	Smartphone microprocessor.	Equivalent. Both devices utilize a smartphone.
Physical Characteristics	Software runs on user's smartphone.	Software runs on user's smartphone.	Equivalent. Both devices utilize a smartphone.
Power	Smartphone plugged into wall outlet with built-in battery back- up.	Smartphone plugged into wall outlet with built-in battery back- up.	Equivalent. Both devices utilize a smartphone.

VII. NON-CLINICAL PERFORMANCE DATA

SleepCheckRx performance data included various verification and validation activities to demonstrate compliance with the applicable FDA guidance documents, including:

- Software verification and validation testing was performed in accordance with the applicable requirements outlined in the *FDA guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005).*
- Cybersecurity verification and validation testing in accordance with the applicable requirements outlined in the FDA guidance *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff (2014).*
- Device Compatibility testing was performed to ensure that compatible smartphones support equivalent performance.
- An evaluation of performance of SleepCheckRx under conditions part of intended use environment (noise, distances, direction, etc.) to verify device effectiveness.
- Human Factors Engineering (HFE) / Usability evaluation was performed in accordance with the applicable requirements of *FDA Guidance. Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff. February 3, 2016*.

VIII. CLINICAL DATA

A prospective, multi-center, single-staged study on the SleepCheckRx algorithm was conducted on 228 adult analyzable subjects.

The clinical study used a binomial endpoint comparing the presence and severity of OSA, by using sleep sounds captured and analyzed by the SleepCheckRx algorithm and comparing them to a simultaneous PSG diagnosis (gold standard). PSG diagnosis was established by independent scorers, in accordance with the Type II (in-home) American Academy of Sleep Medicine (AASM) 2017 Guidelines.

Sleep sound recordings were captured by the SleepCheckRx algorithm throughout the night (minimum of 6 hours) according to the overnight sleep study protocol. Sleep sounds were recorded by a compatible smartphone (loaded with the SleepCheckRx sound recording algorithm) placed on the nightstand, simultaneously with PSG. Each sleep study was scored by a qualified independent sleep scorer.

The mean age of all subjects was 50 years, with a higher percentage of males in the study (63%). The mean BMI was 29.8 and the mean neck circumference of 39.4.

Results of the study (n=220) demonstrated an agreement between SleepCheckRx and clinical diagnosis (using 2 independent PSG scorers) of 109 from 122 subjects (sensitivity 89.3%) with moderate to severe risk of OSA (AHI ≥15), and an agreement of 76 from 98 subjects (specificity 77.6%) with minimal to mild risk of OSA (AHI<15).

There were no adverse events or adverse device effects reported during the study.

IX. Substantial Equivalence discussion

SleepCheckRx has the same intended use as the predicate DROWZLE. Both software platforms are intended to record a patient’s respiratory pattern during sleep for the purpose of prescreening patients for obstructive sleep apnea (OSA) syndrome.

Both devices are designed for use in home-screening adults with suspected possible sleep breathing disorders. The results of both devices are used to assist the healthcare professional in determining the need for further diagnosis and evaluation.

Both devices report the risk of OSA based on a binary output, i.e., either minimal to mild risk of OSA (AHI<15), or moderate to severe risk of OSA (AHI ≥15).

SleepCheckRx is supported by clinical data demonstrating a sensitivity and specificity at the AHI ≥ 15 threshold of 89.3% and 77.6% respectively (n=220) when compared to clinical diagnosis. These results are comparable to the DROWZLE device which reported a sensitivity of 93.7% and specificity of 63% (AHI>15).

X. CONCLUSIONS

Based on the information provided in this submission, the SleepCheckRx is substantially equivalent to the predicate DROWZLE device.