DROWZLE Substantial Equivalence - 510(k) Summary

Submitter's information

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Device/ classification name

The new device trade name and common name are:

- Trade Name: DROWZLE sleep apnea prescreening device
- Common Name: Ventilatory Effort Recorder

21 CFR Reference	Product Code	Class	Generic Device Name	Classification Description
§868.2375	MNR	2	Ventilatory Effort Recorder	Breathing frequency monitor

Predicate device(s)

The predicate device for the DROWZLE screening device is described in the table below.

K Number	Product Code	Class	Device Name	Indications for Use
K112822	MNR	2	Sleep Strip II	The SleepStrip II is intended to measure apnea hypopnea events during sleep for the purpose of prescreening patients for sleep apnea syndrome. The device is intended to be used by adult patients as prescribed by a physician in either home, hospital or facility use settings.

Device description

DROWZLE is a mobile software used to collect symptom data for sleep apnea risk, including severity of daytime sleepiness and personal chronic disease risk factors. DROWZLE also records sleep breathing patterns and sends the sound files to secure servers in the cloud. DROWZLE then analyzes and interprets the sleep breathing results, along with the profile data provided by the individual, to measure and track sleep-related health risks over time.

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DROWZLE Substantial Equivalence Summary, Continued

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.

Technology

DROWZLE is a stand-alone software medical device. It operates on a mobile computing device with an Apple iPhone 7, iPhone 8 or iPhone X using iOS v10.0 or later.

Breathing sounds during sleep are recorded using the microphone within the mobile device. The sound file is uploaded to a cloud server for analysis using the results of standard questionnaires and a proprietary algorithm. A report is generated and provided to the individual and/or their healthcare provider. Reports are provided within the mobile application and/or via email.

Function:	Predicate Device K112822 Sleep Strip II	New Device DROWZLE	Reference Device K963597 Silent Night 1
Intended Use	Home-use device for screening patients with possible sleep disorders	Home-use device for screening patients with possible sleep disorders	Home-use device for screening patients with possible sleep disorders
Indications for Use	The SleepStrip II is intended to measure apnea hypopnea events during sleep for the purpose of prescreening patients for sleep apnea syndrome. The device is intended to be used by adult patients as prescribed by a physician in either home, hospital or facility use settings.	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 Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to record a patient's respiratory pattern. The device is designed for use in home screening of adults with possible sleep disorders.

Function:	Predicate Device K112822 Sleep Strip II	New Device DROWZLE	Reference Device K963597 Silent Night 1
		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.	
Trade/Device Name	SleepStrip II	DROWZLE	Silent Night I
Regulation Number	§868.2375	§868.2375	§868.2375
Regulation Name	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Ventilatory Effort Recorder
Product Code	MNR	MNR	MNR
Target Population	Adults	Adults	Adults
Intended Environment for Use	Home environment	Home environment	Home environment
Method of Measurement	Pressure/flow sensor; thermal sensor	Acoustic analysis of breathing sound	Acoustic analysis of breathing sound
Mode of Action	Analyzes airflow and temperature	Analyzes sound to identify respiratory events indicative of sleep apnea or other disorders	Analyzes sound to identify respiratory events indicative of sleep apnea or other disorders
Sensor placement site	Rests over the lip, under the nose	Smartphone placed within 24 inches of pillow	Microphone #1 is placed near the patient to capture breathing sounds. Microphone #2 is contained in the device to sense ambient room noise.
Sensor elements	3 prongs – two nasal and one oral	Microphone(s) native to smartphone	Microphones
Patient Contact	Yes	Software only. No direct patient contact.	No patient contact during use. Contact with the recording device during set up.
Portability	Yes	Yes	Yes
Recording device	Contained in the device	Mobile device records sound and uploads them into a cloud-based server	Recording device is housed in a metal box consisting of hardware and software.
Measured variable	Oral and nasal airflow	Oral and nasal breath sounds	Oral and nasal breath sounds
Breathing events	Respiration amplitude drops >10 seconds	Breath sound gaps >10 seconds	

Function:	Predicate Device K112822 Sleep Strip II	New Device DROWZLE	Reference Device K963597 Silent Night 1
Sensor attachment	Stick-on adhesive-backed	NA	NA
Display type	LED display	Smartphone display	Liquid crystal display
Breathing Indicator	Blinking light display	None	Not described
Signal loss indicator	Yes, on display	NA	Not described
Breathing interruption counter	126 per hour maximum	No maximum	Not described
Generates a calculated index based on breathing	AHI per sleep period	• Counts gaps in breathing sounds • Calculates Resonea Index	• Counts "Disordered Breathing Events" • Calculates "Respiratory Disturbance Index (RDI)"
Reported Metrics	Counts apnea/hypopnea events	Output: • Number of breathing sound gaps >10 seconds • Average number of >10 second breathing sound gaps per hour • Risk classification based on standard questionnaires: • STOP-BANG • Epworth Sleepiness Scale • Calculated Resonea Index	Output: • Cumulative count of Disordered Breathing Events including snoring, hypopnea, and apnea.
Display function	Result display element	Results are reported to the clinician and patient • Within the mobile device software and • PDF format for printing via email	Results reported on a liquid crystal display. There is no printing capability.
Sleep night use	Single night monitoring	Can be used multiple nights	Single night monitoring
Maximum run-time	5 hours	No maximum run time	Not described
Minimum time required	3 hours	2 hours	Not described
Controller	Hardware and firmware	Smartphone microprocessor	Internal to the box
Airflow signal conditioning	Filtered and digitized	NA	Not described

Function:	Predicate Device K112822 Sleep Strip II	New Device DROWZLE	Reference Device K963597 Silent Night 1
Sampling method	Analog to digital conversion	NA	Not described
Sample rate	10 per second continuous	NA	Not described
Breathing interruption detection criterion	Signal decrease 10 seconds or longer	Breath sounds absent 10 seconds or longer	Not described
Monitor application	Patient self-applied	NA	NA
Download	None – display readout only	Wireless transmission of data to cloud storage for report generation	None – display readout only
Physical Characteristics	Small, non-tether monitor	Software runs on user's smartphone	Box with 2 microphones. 23 cm wide X 17 cm deep X 7.5 cm high
Power	Battery	Smartphone plugged into wall outlet with built-in battery backup	Plugged into wall outlet
Clinical Studies	Clinically tested against PSG	Clinically tested against PSG	Clinically tested against PSG

Non-clinical performance data

As a stand-alone software device non-clinical testing included software verification and validation testing. Usability testing demonstrated the ability of the users to understand the labeling; correctly use the software for recording; and correctly interpret the report.

The DROWZLE software runs on a user-provided mobile device. No biocompatibility testing, electrical safety, or electromagnetic compatibility testing was required.

Clinical performance data

Sound recordings from 242 individuals ≥ 21 years of age undergoing clinically indicated sleep study to assess sleep disordered breathing were collected as part of an IRB-approved clinical study. The study was conducted from 2015-2016 in three AASM accredited laboratories in the United States (NCT03288376).

Each subject had sound recordings from one or more consumer mobile computing device placed on the bedside during PSG. Recordings were made using the standard audio recording function of each device. Separate recording cohorts were used to develop and validate the algorithm used in DROWZLE.

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DROWZLE Substantial Equivalence Summary, Continued

Substantial Equivalence discussion	The new device has the same intended use as the predicate device. Both are intended to be used for identification of adults who may be at risk for sleep apnea and may require further clinical assessment and diagnosis. The new device relies on a different technological assessment to assess the risk of sleep apnea. The predicate device measures nasal and oral air flow and the new device uses the sound generated by that air flow to identify breathing events. Information about a cleared device using the same technology is provided in the comparison table above. The new device was tested against the results of in-lab PSG, providing a sensitivity of 93.7% and specificity of 63% (AHI>15). The inclusion of the results from validated sleep apnea risk questionnaires reinforces the effectiveness by providing additional means of assessing risk, further reducing the potential for false negative results.
Conclusions	Based on the similarity in function and clinical performance, it is concluded that DROWZLE is substantially equivalent to the predicate device.