DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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WO66-G609
Silver Spring, MD 20993-002

July 21, 2015

inSleep Technologies, LLC (inSleep Health)
C/O Ms. Adrienne Lenz
Senior Consultant, Quality Assurance and Regulatory Affairs
Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K150365
Trade/Device Name: Cloud 9® System
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-Continuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: June 15, 2015
Received: June 22, 2015

Dear Ms. Lenz:

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" (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 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental 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)*
K150365

Device Name
Cloud9® System

Indications for Use *(Describe)*
The Cloud9® System is indicated for use by adults to reduce or eliminate simple snoring. The Cloud9® System maintains a continuous, positive low-pressure in the airway. The device is designed for prescription home use.

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.

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510(k) Summary

for

Cloud9® System

K150365

1. Submission Sponsor

inSleep Health
12100 Singletree Lane
Suite 183
Eden Prairie, MN 55344
USA
Phone: (952) 746-1324
Fax: (954) 888-9600
Contact: Marty Kerber, SVP, Engineering and Manufacturing

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: PHONE
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Adrienne Lenz, Senior Consultant, Quality Assurance and Regulatory Affairs
Email: project.management@emergogroup.com

3. Date Prepared

June 12, 2015

4. Device Identification

Trade/Proprietary Name:	Cloud9® System
Common/Usual Name:	Continuous positive airway pressure (CPAP)
Classification Name:	Noncontinuous ventilator (IPPB)
Classification Regulation:	868.5905
Product Code:	BZD, ventilator, non-continuous (respirator)
Device Class:	Class II
Classification Panel:	Anesthesiology

5. Legally Marketed Predicate Device(s)

Main Predicate K100121 AEIOMED Model 300157 CPAP System (now marketed by Somnetics as Transcend)

K132013 Resmed Swift Air (now marketed as AirFit P10).

6. Device Description

The Cloud9® System is a device for delivery of low levels of continuous positive airway pressure (CPAP) that can be used by people who wish to reduce or eliminate their snoring. Its main components include the airflow unit (AFU) and custom nasal mask interface, called the NiteCap™. The Cloud9® System delivers CPAP at low pressures ranging from 2 to 4 cmH_20, via a nasal interface. The blower generating the airstream is controlled continuously based on pressure measurements at the nasal interface to maintain the pressure at the nose of the user constant ("CPAP"). Its performance is similar to currently used CPAP devices.

7. Indication for Use Statement

The Cloud9® System is indicated for use by adults to reduce or eliminate simple snoring. The Cloud9 System maintains a continuous, positive low-pressure in the airway. The device is designed for prescription home use.

8. Substantial Equivalence Discussion

The following table compares the Cloud9® System to the predicate devices with respect to indications for use, intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**inSleep Health**	**Somnetics (cleared by AEIOMED)**	**Resmed**	**SIGNIFICANT DIFFERENCES**
Trade Name	Cloud9® System	Model 300157 CPAP System (now marketed as Transcend)	Swift Air (now marketed as AirFit P10)	
510(k) Number	This submission	K100121	K132013	None
Product Code	BZD	BZD	BZD	None
Regulation Number	868.5905	868.5905	868.5905	None
Regulation Name	Noncontinuous ventilator (IPPB)	Noncontinuous ventilator (IPPB)	Noncontinuous ventilator (IPPB)	None

Manufacturer	inSleep Health	Somnetics (cleared by AEIOMED)	Resmed	SIGNIFICANT DIFFERENCES
Trade Name	Cloud9® System	Model 300157 CPAP System (now marketed as Transcend)	Swift Air (now marketed as AirFit P10)	
Indications for Use	The Cloud9® System is indicated for use by adults to reduce or eliminate simple snoring. The Cloud9® device maintains a continuous, positive low-pressure in the airway. The device is designed for prescription home use.	The Model 300157 CPAP System is a single patient reusable device. The Model 300157 CPAP System provides continuous positive airway pressure (CPAP) to support treatment of adults (over 30 kg) with Obstructive Sleep Apnea.	The Swift Air channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device. The Swift Air is: * to be used by patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed * intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.	The Cloud9® System's indication is similar to the Invent (K120665) which provides expiratory positive airway pressure to reduce or eliminate snoring.
Mechanism of Action	Continuous Positive Airway Pressure (CPAP)	Continuous Positive Airway Pressure (CPAP)	Continuous Positive Airway Pressure (CPAP) or BiLevel Positive Airway Pressure (BiPAP)	None
Technology	Blower Nasal mask held in place with adjustable headgear that straps the mask to the face.	Blower Nasal mask held in place with adjustable headgear that straps the mask to the face.	Nasal mask held in place with adjustable headgear that straps the mask to the face.	None

Manufacturer	inSleep Health	Somnetics (cleared by AEIOMED)	Resmed	SIGNIFICANT DIFFERENCES
Trade Name	Cloud9® System	Model 300157 CPAP System (now marketed as Transcend)	Swift Air (now marketed as AirFit P10)	
CPAP Type	User adjustable fixed CPAP pressure	Auto CPAP	NA – channels airflow noninvasively to a patient from a PAP device such as a CPAP or bilevel device.	A prescribed pressure is not required for this indication and therefore users can select the pressure that works best to reduce or eliminate their snoring.
Patient Circuit Connection	Custom connector (15 mm ID) that includes the measurement lumen in one single connector	Air outlet connector port: 19-mm diameter proprietary connector Universal Adapter Port Dimensions 22-mm diameter connector	Conical connectors (ref. ISO 5356-1:2004).	The Cloud9®System's circuit includes a second small lumen to measure pressure at the nose and a custom connector prevents patients from using another, not approved circuit with the Air Flow Unit.
Pressure Range	2 to 4 cm H_2O	4 to 20 cm H_2O	4 to 20 cm H_2O	Lower maximum pressure (4 cm H_2O) for the treatment of snoring. Other CPAP devices, such as DeVilbiss Intellipap (K071689) also use lower pressures, down to 3 cmH_2O.
Pressure Stability (cmH2O) as measured by ISO 17510-1	Less than +/-1 cm H_2O at all pressure levels	Not specified	Not applicable to interface	Cloud9 meets requirements of ISO 17510-1 like other CPAP devices.

Manufacturer	inSleep Health	Somnetics (cleared by AEIOMED)	Resmed	SIGNIFICANT DIFFERENCES
Trade Name	Cloud9® System	Model 300157 CPAP System (now marketed as Transcend)	Swift Air (now marketed as AirFit P10)	
Maximum Flow (LPM)	71 L/min for all pressure settings	71 L/min at 4cmH_2O, 75 L/min at 8cmH_2O	Not applicable to interface	Cloud9 meets requirements of ISO 17510-1 like other CPAP devices.
Maximum System Shutdown Pressure	30 cm H_2O	30 cm H_2O	Not applicable to interface	None
Mask Sizes	InSleep nasal interface (the Butterfly) is available in Small, Medium, Large and Extra Large (S, M, L & XL)	K100121 includes a patient interface, but details are not publically available.	AirFit P10 XS, S,M, L AirFit P10 for Her XS, S, M,L	Both are available in various sizes to fit different users.
Mask Dead space	Less than 52 ml	Seal dead space Less than 301 cc	Large pillows 123 mL.	The Cloud9® System dead space is lower and thus better than the predicate device
Resistance/ Drop in pressure as measured according to 17510-2	at 50 L/min: 5.7 cm H_2O at 100 L/min: 21.1 cm H_2O	At 50 l/min 0.140 cm H2O At 100 l/min 0.278 cm H2O	at 50 L/min: 0.4 cm H2O at 100 L/min: 1.4 cm H2O	The Cloud9® System is working with smaller hoses which increases the resistance. The Cloud9® mask and interface can therefore only be used with the Cloud9® AFU, that is specifically designed to work with the higher resistance mask.

Manufacturer	inSleep Health	Somnetics (cleared by AEIOMED)	Resmed	SIGNIFICANT DIFFERENCES
Trade Name	Cloud9® System	Model 300157 CPAP System (now marketed as Transcend)	Swift Air (now marketed as AirFit P10)	
AC Powered	100 – 240VAC 50-60hz	Input 100-240 VAC, 50-60Hz Output 19VDC, 2.6 Amp	Not applicable to interface	The Cloud9® System meets the same standards for electrical safety and electromagnetic compatibility as its predicate devices.
Materials	Comply with ISO 10993-1	Comply with ISO 10993-1	Comply with ISO 10993-1	None

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Cloud9® System and in showing substantial equivalence to the predicate devices, inSleep Health completed a risk analysis and a number of tests. The Cloud9® System meets all the requirements for overall design, cleaning, biocompatibility, electrical safety and software and test results confirm that the output meets the design inputs and specifications. The Cloud9® System passed all testing as shown by the acceptable results obtained.

The Cloud9® System complies with the applicable voluntary standards for biocompatibility, electrical safety, usability and CPAP performance. The device passed all the testing in accordance with the following international standards.

- ISO 10993-1: 2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
- IEC 60601-1: 2005, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 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 60601-1-11:2010, 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
- ISO 17510-2: 2007: Sleep apnoea breathing therapy -Part 2: Masks and application accessories
- ISO 17510-1: 2007: Sleep Apnoea Breathing Therapy. Part 1: Sleep Apnoea Breathing Therapy Equipment.
- IEC 62366: 2007 Medical devices - Application of usability engineering to medical devices

- IEC 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability
- IEC 62304: 2006, Medical device software - Software life cycle processes
- ISO 14971: 2007, Medical devices -- Application of risk management to medical devices

Table 5B summarizes the biocompatibility testing performed.

Table 5B – Biocompatibility Testing

Part Name	Contact Type/Duration	Tests Conducted
Air Circuit	Skin - Permanent duration (>30 days) based on cumulative contact every night. AND Airway gas – humidified due to patient exhalation (considered external communication with tissue) permanent duration (>30 days) based on cumulative contact every night	• Cytotoxicity • Sensitization • Irritation/ intracutaneous reactivity • System toxicity (acute) • Pyrogenicity (as part of Systemic toxicity) • Subchronic toxicity (subacute toxicity) • Genotoxicity • Implantation • Chemical Characterization (identification of extractable compounds)
Main Hose	Skin – Permanent duration (>30 days) based on cumulative contact every night. AND Airway gas – dry.	• Cytotoxicity • Sensitization • Irritation/ intracutaneous reactivity • Chemical Characterization (identification of particulates and VOCs)
Air flow unit internal components	Airway gas – dry. No direct patient contact	• Chemical Characterization (identification of particulates and VOCs)
NiteCap™ Fit System - Sport / Athletic	Skin – Permanent duration (>30 days) based on cumulative contact every night.	• Cytotoxicity • Sensitization • Irritation/ intracutaneous reactivity

Additional verification and validation testing included:
- Validation of cleaning methods
- Validation to demonstrate that all features of the Cloud9 System were compliant with the system, software and firmware level requirements.
- Testing of the usability of the Cloud9 System to evaluate the ability of an adult to unpack, assemble, operate and disassemble the Cloud9® System safely and effectively.

- Environmental testing to evaluate the use of Cloud9's Air Flow Unit in a variety of environmental conditions.
- Testing to determine the 6-month recommended change interval for the Cloud9® System's Filter Assembly.
- Verification that the cleaning methods do not affect device performance over the claimed lifetime or replacement intervals
- Verification of the maximum pressure under single fault conditions
- Verification of the maximum temperature at the patient connection port under normal and single fault conditions

10. Clinical Performance Data

A clinical study was conducted to evaluate safety and efficacy of the Cloud9® System to reduce or eliminate simple snoring. The study was a prospective, interventional study of habitual simple snorers with subjects serving as their own controls. The overall design involved four subject visits as follows:

1. Baseline assessment of snoring and sleep parameters by PSG
2. Titration study to determine the lowest effective level of CPAP within the range of 2 to 6 cm H_2O
3. Full treatment night at the previously determined CPAP level (Visit 2)
4. Second control night off CPAP to assess and change from baseline over the course of the trial.

Device safety was assessed by the occurrence of adverse events (nasal or skin irritation, epistaxis and sleep disruption) noted during device use (Visits 2 and 3).

A total of 24 subjects were evaluated at three centers. Table 5C presents the study endpoints, results and conclusions.

Table 5C – Study Results and Conclusions

Study Endpoint	Result	Conclusion
Primary – Reduction in the number of all snores or reduction in loud snores as percent of sleep time with the device (Visits #2 and #3). *Success criteria: 50% reduction in all snores OR at least a 90% reduction in loud snores as a percent of sleep time*	There was an average of 86% reduction in loud snoring and 67% reduction in all snoring	The Cloud9 System is effective for its indication to reduce or eliminate simple snoring. The primary endpoint was met with a greater than 50% reduction in all snores.
Secondary – Reduction in overall nightly noise exposure below the WHO limit of 45 dBA. *Success criteria: 50% reduction in snoring time ≥ 45 dBA*	Loud snoring was reduced from 34% of sleep time to 5% of sleep time with the Cloud9™ and the total time spent in loud snoring was reduced from 148 minutes to 18 minutes, a greater than 50% reduction.	The Cloud9 System is effective for its indication to reduce or eliminate simple snoring. The secondary endpoint was met with a greater than 50% reduction in snoring time ≥ 45 dBA (loud snoring).
Safety – No adverse events (nasal or skin irritation, epistaxis and sleep disruption) noted	No adverse events occurred during this study.	The safety endpoint was met.

11. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the difference between the Cloud9® System and the predicate devices do not raise any questions regarding its safety and effectiveness. The Cloud9® System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.