June 5, 2018

NightBalance BV
% Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hilsborough, CA 94010

Re: K180608
Trade/Device Name: Lunoa System
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: MYB
Dated: March 5, 2018
Received: March 7, 2018

Dear Cindy Domecus, R.A.C. (Us & Eu):

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.

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.

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 yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180608

Device Name
Lunoa System

Indications for Use *(Describe)*
The Lunoa System is indicated for prescription use for the treatment of adult patients with positional obstructive sleep apnea with a non-supine apnea-hypopnea index <20. It records position and movement so that positional changes in sleep quality can be assessed.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21 CFR 807.92.

I. 510(k) OWNER

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Submission Correspondent:
Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
DomecusConsutling@comcast.net

Date Summary Prepared: May 7, 2018

II. DEVICE

Name of Device: Lunoa System
Common or Usual Name: Sleep position therapy device
Classification Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (21 CFR 872.5570)
Regulatory Class: II
Product Code: MYB

III. PREDICATE DEVICE

Name	Manufacturer	510(k)a #
Night Shift	Advanced Brain Monitoring	K140190

IV. DEVICE DESCRIPTION

The Lunoa System is a rechargeable battery-operated medical device, worn around the chest in an elasticized chest strap (Figure 1), intended to keep patients with positional obstructive sleep apnea (POSA) from sleeping in the supine position. The System consists of a sensor device, chest strap, docking station, power adapter, travel case, and portal.

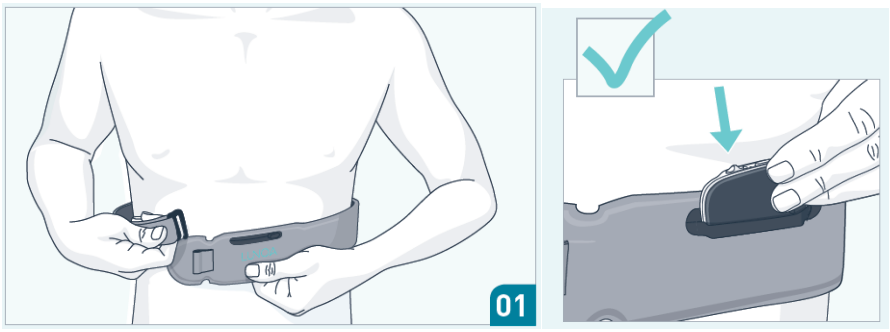

Figure 1 Lunoa System worn around chest

Sensor Device

The Sensor Device (Figure 2) is battery-operated and contains a digital accelerometer that continually monitors a patient's sleep position. When using the device, if a patient turns to the supine position, it will react with a soft vibration that continues until the patient returns to a non-supine position.

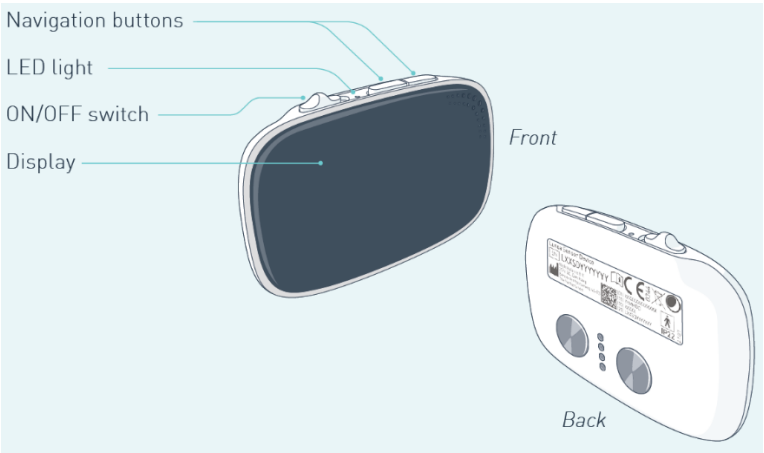

Figure 2 Sensor Device

The Sensor Device includes an organic light emitting diode (OLED) display that allows patients to view the following information (Figure 3):

- Percentage of supine sleep from the previous night of sleep with an indication of either an increase or decrease in percentage of supine sleep
- Number of vibrational feedback instances from the previous night of sleep
- Trend report with indication of average percentage supine sleep in the previous 7 days and a graphical visualization of the trendline

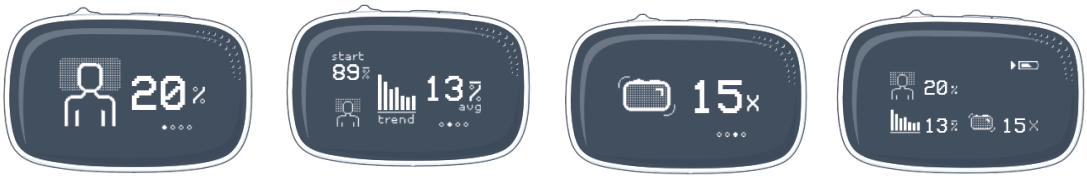

Figure 3 Display examples

Chest Strap

The Chest Strap (Figure 4) has a pocket to hold the Sensor Device and is worn around the patient's chest each night.

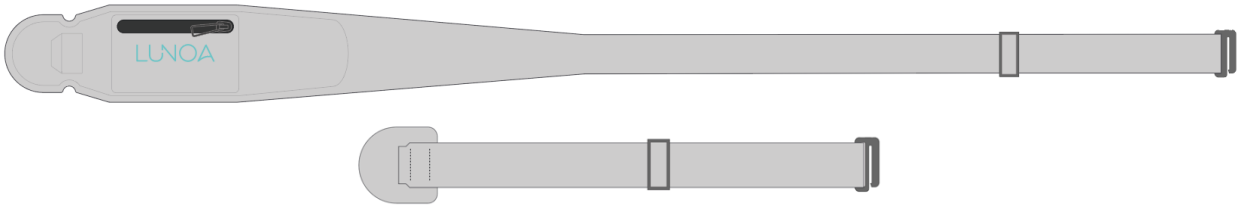

Figure 4 Chest Strap & Extension Piece

Docking Station

A Docking Station (Figure 5) recharges the Sensor Device when not in use, downloads and stores patient data from the Sensor Device. It then encrypts and transmits the data to the Portal through a cellular network connection. This data is then rendered into readable format on the Portal for the user.

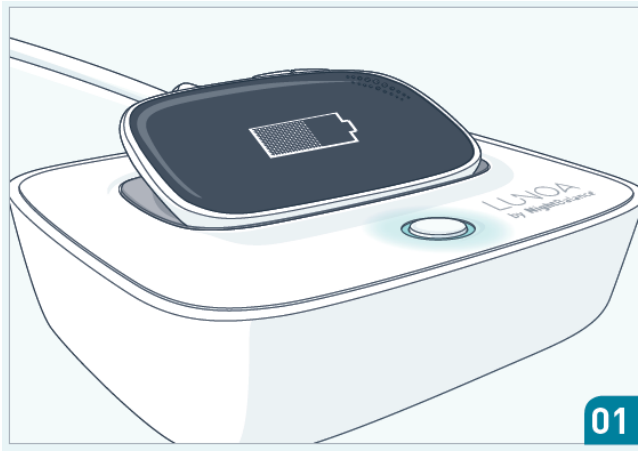

Figure 5 Docking Station with docked Sensor Device

Power Adapter
The medical-grade power adapter plugs into the Docking Station and provides power to operate the Docking Station and recharge the Sensor Device.

Travel Case
The Travel Case stores the Sensor Device, Chest Strap, Docking Station, IFU, and Power Adapter during travel or storage.

Portal
The Portal allows users to view data downloaded from the Sensor Device. Access is based on permissions configured in the individual account setups. Consent to data sharing is included in the account setup process.

V. INDICATIONS FOR USE

The Lunoa System is indicated for prescription use for the treatment of adult patients with positional obstructive sleep apnea with a non-supine apnea-hypopnea index <20. It records position and movement so that positional changes in sleep quality can be assessed.

The Indications for Use statement for the Lunoa System is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices are intended to keep patients with positional obstructive sleep apnea (POSA) from sleeping in the supine position.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate devices are intended to keep patients with positional obstructive sleep apnea (POSA) from sleeping in the supine position. When using the devices, if a patient turns to the supine position, both will react with a soft vibration that continues until the patient returns to a non-supine position. At a high level, the subject and predicate devices are based on the following same technological elements:

- Sensor worn on the body attached via a strap
- Sensor powered by a rechargeable battery
- Vibro-tactile feedback with increasing intensity when user is detected to be sleeping supine
- Ability to download data, perform data analysis, and present data on a web portal

The following technological differences exist between the subject and predicate devices:

- The subject device is positioned on the patient’s chest; the predicate device is positioned on the back of the patient’s neck
- The subject device uses a polyamide, Lycra, polyester strap; the predicate device uses a silicone strap

- The predicate device assesses snoring; the subject device does not
- The subject enclosure is cleaned with a damp cloth; the predicate enclosure is cleaned with alcohol wipes

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Lunoa System was conducted in accordance with the FDA's guidance document titled, "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process'", June 16, 2016. The following tests were completed:

- Cytotoxicity
- Sensitization
- Irritation

The Lunoa System's chest strap is a "surface device" contacting intact skin for a limited duration (<24 hours each day).

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Lunoa System, consisting of the Sensor Device and Docking Station. The Lunoa System complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". The software for this device was considered a "moderate" level of concern, since a failure or latent flaw in the software could lead to a delay in delivery of appropriate medical care that would likely lead to minor injury.

Mechanical testing

- The sensor device was tested to verify it is quiet, can be charged by the docking station, and can be cleaned.
- The docking station was tested to verify it is compatible with the sensor device, can be powered by the power adapter, and can be cleaned.

- The chest strap was tested to verify it can be worn by users with a broad range of chest sizes, can be washed on a weekly basis, can last through at least 1 year of use, and is compatible with the sensor device.
- The labeling was tested to verify they are legible, durable, compliant with regulations, and compatible with the packaging.
- The packaging was tested to verify it is compatible with the labeling, can be placed on a pallet for distribution, and can be shipped without damage.
- The travel case was tested to verify it is compatible with the Lunoa System and will last at least 3 years.

Clinical Studies

Eight investigator-initiated clinical studies have been conducted to evaluate the safety and effectiveness of the Lunoa System. Study designs ranged from single arm, cohort trials to prospective, randomized, parallel, cohort studies. Active control arms were included in three of the randomized, controlled studies to compare mandibular advancing devices and bulky backpack type devices (Rematee, manufactured by Rematee, the Snore Shirt, Inc.). Durability of treatment has been measured in 1 to 12-month home use periods. **Tables 5-1 & 5-2** below provide a summary of the studies conducted.

Table 5-1: Summary of Clinical Studies

Author	Study design	Follow-up period	Arms	# of patients	Endpoints	Study Location
Single Arm Trials						
Van Maanen et al. 2013[i]	Single arm, cohort study	1 month	SPT v1.1 only	31	• ESS • FOSQ • PSG: AHI, % Supine sleeping time, etc. • Compliance	Amsterdam, the Netherlands.
Van Maanen & De Vries 2014[ii]	Prospective, single arm, multicenter cohort study	6 months	SPT v1.1 only	106	• ESS • FOSQ • PSQI • PSG: AHI, % Supine sleeping time, etc. • Compliance	Amsterdam, The Netherlands.
Benoist et al. 2016[iii]	Prospective, single arm, cohort study	3 months	SPT v1.1 after surgery	33	• ESS • PSG: AHI, % Supine sleeping time etc	Amsterdam, the Netherlands

Randomized, Controlled Trials						
Eijsvogel et al. 2015[iv]	Prospective, randomized, parallel, cohort study	1 month	SPT v1.1 vs Tennis Ball Technique (TBT)	21 TBT 27 SPT	• ESS • QSQ • PSG: AHI, % Supine sleeping time etc • WASO • Compliance	Enschede, The Netherlands
Dieltjens et al. 2015[v]	Prospective, randomized, parallel	4 nights; 1 baseline & 1 per treatment (combo)	SPT v1.1 vs Oral Appliance (OA) & combo SPT+OA	20	• Subjective preference questionnaire • PSG: AHI, % Supine sleeping time etc	Edegem, Belgium
Benoist & de Ruiter et al. 2016[vi]	Prospective, randomized, multicenter	3 months	SPT v1.1 vs OA	81	• ESS • FOSQ • PSG: AHI, % Supine sleeping time etc • Compliance	Amsterdam, The Netherlands
Laub et al. 2016[vii]	Prospective, randomized, parallel	6 months	SPT v1.1 vs non-treatment control	52 SPT 49 non	• ESS • PSG: AHI, % Supine sleeping time etc. • Experience questions	Glostrup, Denmark
De Ruiter et al. 2017[viii]	Prospective, randomized, multicenter	12 months	SPT vs MAD	29 SPT 29 MAD	• ESS • FOSQ • PSG: AHI, % Supine sleeping time etc • Compliance	Amsterdam, Netherlands

Table 5-2: Results Summary

Publication	Median % Supine Sleep Time (STS)	Median AHI	ESS	FOSQ	Compliance
Van Maanen et al. 2013	Median % STS decreased from 49.9% to 0.0%	Median AHI decreased from 16.4 to 5.2	Decreased significantly	Increased significantly	92.7%
Van Maanen & De Vries 2014	Median % STS decreased from 21% to 2.0 %	NR	Decreased significantly	Increased significantly	71.2%
Benoist et al. 2016	Median % STS decreased from 40.1% to 7.4%	Median AHI decreased from 18.3 to 12.5	Decreased significantly	NR	89%
Eijsvogel et al. 2015	Median % supine sleep time decreased from 31.1% to 0 %	Median AHI decreased from 13.1 to 5.8	No change between groups	NR	75.9%
Dieltjens et al. 2015	Median % STS decreased from 31.9% to 0%	Median AHI decreased from 20.8 to 11.1. SPT + MAD reduced to 5.7	NR	NR	NR
Benoist & de Ruiter et al. 2016	Median % STS decreased from 43.0% to 11%	Median AHI decreased from 13.0 to 7.0	No significant change	No change between groups	89.3%
Laub et al. 2016	Mean % STS decreased from 47% to 17%	Mean AHI decreased from 18 to 10	No significant change	NR	75.5%
De Ruiter et al. 2017	Mean % STS decreased from 41.6% to 12.7%	Mean AHI decreased from 13.2 to 7.1	No significant change	No significant change	100%

The clinical data for the Lunoa System demonstrate that the Lunoa System performs as intended, is safe and effective for its intended use, and provides similar safety and effectiveness results to the predicate device.

VIII. CONCLUSION

Based on the intended use, technological characteristics, and performance data provided in this premarket notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

[i] van Maanen JP, Meester KA, Dun LN, Koutsourelakis I, Witte BI, Laman DM, et al. The sleep position trainer: a new treatment for positional obstructive sleep apnoea. Sleep & breathing. 2013;17(2):771-9.

[ii] van Maanen JP, de Vries N. Long-term effectiveness and compliance of positional therapy with the sleep position trainer in the treatment of positional obstructive sleep apnea syndrome. Sleep. 2014;37(7):1209-15.

[iii] Benoist LB, Verhagen M, Torensma B, van Maanen JP, de Vries N. Positional therapy in patients with residual positional obstructive sleep apnea after upper airway surgery Sleep Breath. 2016 Aug 17. [Epub ahead of print]

[iv] Eijsvogel MM, Ubbink R, Dekker J, Oppersma E, de Jongh FH, van der Palen J, et al. Sleep position trainer versus tennis ball technique in positional obstructive sleep apnea syndrome. Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine. 2015;11(2):139-47

[v] Dieltjens M, Vroegop AV, Verbruggen AE, Wouters K, Willemen M, De Backer WA, et al. A promising concept of combination therapy for positional obstructive sleep apnea. Sleep & breathing = Schlaf & Atmung. 2015;19(2):637-44.

[vi] Benoist LBL, de Ruiter MHT, de Lange J, de Vries N, et al. A randomized controlled trial of positional therapy versus oral appliance therapy for position-dependent sleep apnea. Sleep Medicine 34 (2017) 109-117

[vii] Laub RR, Tonnesen P, Jennum PJ. A Sleep Position Trainer for positional sleep apnea: a randomized, controlled trial. J Sleep Res. (2017) DOI 10.1111/jsr.12530

[viii] De Ruiter MHT, Benoist LBL, et al. Durability of treatment effects of the Sleep Position Trainer versus oral appliance therapy in positional OSA: 12-month follow-up of a randomized controlled trial. Sleep Breath DOI 10.1007/s11325-017-1568-4