July 11, 2022

Sibel Inc.
Peter Xu
Chief Operating Officer
6650 W. Touhy Ave.
Niles, Illinois 60714

Re: K220095
Trade/Device Name: ANNE Sleep
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: June 7, 2022
Received: June 8, 2022

Dear Peter Xu:

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
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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)*
K220095

Device Name
ANNE Sleep

Indications for Use *(Describe)*
ANNE Sleep is a wearable sensor system intended for use in the collection, analysis, display, and storage of physiological parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use in the clinical and home setting under the direction and interpretation by a Healthcare Professional (HCP).

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

I. Submitter:

Sibel Inc.
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Official Correspondent:
Sarah Coughlin, Regulatory Affairs and Quality Assurance Engineer
6650 W. Touhy Avenue, Niles, IL 60714
Tel: (224) 251-8859

Date Prepared: 7/10/2022

II. Device Information

Name of Device: ANNE Sleep

510(k) Number: K220095

Classification Name: Breathing Frequency Monitor

Regulation: 21 CFR §868.2375

Regulatory Class: Class II

Product Classification Code: MNR

III. Predicate Device

Trade Name: WatchPAT One
510(k): K183559
Device Manufacturer: Itamar Medical, Ltd.

IV. Reference Device

Trade Name: ANNE One
510(k): K211305
Device Manufacturer: Sibel Inc.

V. Device Description

ANNE Sleep is a wireless physiological recorder for use as an aid in the diagnosis of sleep-related breathing disorders by healthcare professionals. The system features two skin-mounted, bio-integrated sensors that pair with an associated proprietary software application for the transmission and storage of data. The sensors, which are placed on the chest and finger, measure peripheral arterial tonometry (PAT), oximetry (SpO_2), pulse rate, snoring, chest movement, body position, total sleep time, and heart rate. These data are uploaded to a cloud backend that can communicate with a compatible third-party software viewer, where they are reviewed by a

qualified healthcare professional to identify sleep-disordered breathing events according to a scoring manual. The number of sleep-disordered breathing events per hour of sleep is the Sibel-AHI, a parameter that functions as an aid to diagnosis of sleep apnea by physicians. A sleep report is generated from this score and uploaded to a web portal, the ANNE Sleep Hub, where it can be stored and further reviewed.

VI. Indications for Use

ANNE Sleep is a wearable sensor system intended for use in the collection, analysis, display, and storage of physiological parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use in the clinical and home setting under the direction and interpretation by a Healthcare Professional (HCP).

	Subject device **ANNE Sleep**	**Primary predicate device** **Itamar Medical, Ltd.**	**Reference device** **Sibel Inc.**	**Variances / Equivalence**
Trade Name	ANNE Sleep	WatchPat One	ANNE One	
510(k) Number	K220095	K183559	K211305	N/A
Class	II	II	II	**Equivalent**
Product Code	MNR	MNR	DRG, MWI, FLL	**Equivalent** ANNE Sleep's product code is equivalent to WatchPat One.
Regulation Number and Regulation Name	868.2375 Breathing Frequency Monitor	868.2375 Breathing Frequency Monitor	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	**Equivalent** ANNE Sleep's regulation number and name is equivalent to WatchPat One.
Indications for Use	ANNE Sleep is a wearable sensor system intended for use in the collection, analysis, display, and storage of physiological parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use in the clinical and home setting under the direction and interpretation by a Healthcare Professional (HCP).	The WatchPAT One (WP1) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep, and Wake), snoring level, and body position. The WP1 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and snoring level and body position discrete states	ANNE One is a wireless vital signs and physiological data monitoring platform indicated for the measurement of heart rate, respiratory rate, step count, fall count, skin temperature, and body temperature by qualified healthcare professionals in healthcare settings. The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment. The device is not intended for use on critical care patients. The device is not intended to monitor or measure respiratory rate or	**Substantially Equivalent** ANNE Sleep's intended use and indications for use do not include sleep staging or the discrimination between central and obstructive sleep apneic events.

		from an external integrated snoring and body position sensor. The WP1's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP1's PSTAGES and snoring level and body position are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.	heart rate on ambulatory patients.	
Target Population	22 years of age and older	PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.	Adults, 18 years of age and older	**Substantially Equivalent** The ANNE Sleep target population is more restrictive than WatchPAT One.
Use Environment	Recording in the home environment with the report and interpretation performed in the clinical setting.	Recording in the home environment with the report and interpretation performed in the clinical setting.	Hospital Setting	**Equivalent** The intended use environment for ANNE Sleep is equivalent to WatchPAT One.
Sensor Placement	Finger and Chest	Finger, Chest, and Wrist	Finger and Chest	**Substantially Equivalent** ANNE Sleep does not have a sensor located on the wrist
Components	Limb Sensor Chest Sensor Accelerometer ECG Module PPG Module ANNE Sleep Application Software	uPAT Finger Probe Actigraph Controller Microphone Accelerometer ZzzPAT Software Chest Sensor	Limb Sensor Chest Sensor Accelerometer ECG Module ANNE View Application Software	**Substantially Equivalent** ANNE Sleep does not include a microphone or controller. Performance testing demonstrates that this difference does not influence overall safety and effectiveness.

	ANNE Hub Software			
Channels	PAT Pulse Rate Oximetry Snoring Body Position Chest Movement Heart Rate	PAT Pulse Rate Oximetry Actigraphy Snoring Body Position Chest Movement	Heart Rate Respiratory Rate Body Position Temperature	**Substantially Equivalent** ANNE Sleep collects the same channels as WatchPAT One, as well as heart rate, which is supported by the reference device
Analysis Outputs	Sibel-AHI (based on manual scoring of data by HCP) Body Position Discrete States Heart Rate Total Sleep Time SpO_2	pRDI pAHI pAHIc Sleep Stages Snoring Level Body Position Discrete States	Heart Rate Respiratory Rate Step Count Fall Count Temperature	**Substantially Equivalent** Sibel-AHI is a device specific approximation of AHI that is manually scored by an HCP and is similar to the pAHI value that is automatically calculated by WatchPAT. ANNE Sleep is not intended for sleep staging or the discrimination between central and obstructive sleep apneic events. Snoring level and pRDI are supplemental parameters that are not directly utilized in the diagnosis of sleep disordered breathing. Performance testing of SpO_2 and heart rate measurements with ANNE Sleep demonstrate that output of these parameters do not influence the overall safety and effectiveness of the device.
Performance	Pulse Rate: 30-300 bpm ± 3 bpm Heart Rate: 30-300 bpm ± the greater of ± 10% or ± 5 bpm SpO_2: A_{RMS} ≤ 3% (range 70-100%)	Pulse Rate: 30-150 bpm ± 1 bpm SpO_2: A_{RMS} ≤ 3% (range 70-100%)	Heart Rate: 30-270 bpm ± the greater of ± 10% or ± 5 bpm Temperature: 73.4°F - 109.4°F ± 0.54°F	**Substantially Equivalent**

	Aid to Diagnosis of Moderate to Severe OSA (AHI≥15): Sensitivity 90%, Specificity 98%			
Data Collection and Transfer	Patient data is wirelessly transferred via Bluetooth from the sensors to a mobile phone. Data is then wirelessly transferred from the phone to the cloud when connected to the internet.	Patient data is wirelessly transferred via Bluetooth from the sensors to a mobile phone. Data is then wirelessly transferred from the phone to the cloud when connected to the internet.	Data transmitted wirelessly via Bluetooth from sensors to mobile device	**Equivalent** Data collection and transfer with ANNE Sleep is equivalent to WatchPAT One.
Recording Capacity	36 hours of continuous use	Approx. 10 hours	36 hours of continuous use	**Equivalent** ANNE Sleep is equivalent in recording capacity to ANNE One. Differences between WatchPAT One and ANNE Sleep do not influence safety or effectiveness as both can operate over a full night of sleep.
Energy Source	Rechargeable Lithium Polymer Battery	One OTS 1.5V Alkaline AAA Battery	Rechargeable Lithium Polymer Battery	**Equivalent**
Analysis Software	Analysis performed off the recording device, on a compatible cloud-based software platform.	Analysis performed off the recording device, on the PC or cloud-based by the zzzPAT software.	None	**Substantially Equivalent**

VII. Clinical Studies

SpO_2 Accuracy: Sibel validated the accuracy of SpO_2 measurements compared to blood gas analysis in n=12 healthy subjects over the range of 70-100% oxygen saturation according to Section 201.12.1 of ISO 80601-2-61 and Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff, Issued March 2013. Enrolled subjects had skin tones varying from Fitzpatrick 2-5, with two subjects having darker skin pigmentation (Fitzpatrick 5). The average root mean square error (A_{RMS}) was 2.31%, meeting the requirements of the above-mentioned standard.

Comparison to PSG: The performance of the ANNE Sleep system as a diagnostic aid for moderate to severe obstructive sleep apnea (OSA) in adults was evaluated compared to the gold standard, polysomnography (PSG), in a single-arm, open-label, multi-center clinical study with n=225 subjects that was conducted in the United States. Subjects were representative of the intended target population, including individuals 22 years of age or older who are suspected of having OSA. Subjects were 44% male and 56% female. Subjects were 73% white, 12% Black or African American, 9% Asian, 0.4% American Indian or Alaska Native, and 4% multi-racial. The results of the study indicate that ANNE Sleep is sufficiently accurate as an aid to the diagnosis of moderate to severe OSA, with a sensitivity and specificity of 90% and 98%, respectively. Additionally, skin tolerance was assessed following removal of the chest sensor for n=184 patients. No evidence of increased breakdown or skin dryness was reported, and only a small average increase in temporary redness was observed in 32% of subjects. No adverse events were reported during the study.

VIII. Performance Data

The following consensus standards and bench testing were used to evaluate the safety and effectiveness of ANNE Sleep:

- Electrical safety and electromagnetic compatibility testing according to ANSI/AAMI ES60601-1:2005/(R)2012 and IEC 60601-1-2:2014 standards. Electrical safety testing in the home healthcare environment per IEC 60601-1-11:2015.
- Safety and Performance testing of pulse oximeter per ISO 80601-2-61:2017.
- Biocompatibility testing according to ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-10:2010 for new patient contacting materials.
- Wireless coexistence testing according to ANSI IEEE C63.27-2017.
- Software verification and validation testing according to IEC 62304:2015 and the FDA guidance document, Content of Premarket Submissions for Software Contained in Medical Devices.
- Shelf life testing of the adhesive to demonstrate safe and effective performance over the intended device life cycle.
- Bench testing to demonstrate the mechanical durability of the sensors.
- Usability testing in accordance with the FDA guidance document, Applying Human Factors and Usability Engineering to Medical Devices
- Performance testing of heart rate, body position, PAT, pulse rate, perfusion index, snore, total sleep time, and chest movement parameters.
- Performance testing to demonstrate the precision and repeatability of the system over multiple nights of sleep.

- Cybersecurity evaluation according to the requirements of the FDA draft guidance document, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Assessment of Software of Unknown Provenance per the FDA guidance document, Off-The-Shelf Software Use in Medical Devices

IX. Summary

ANNE Sleep is substantially equivalent to its predicate, the WatchPAT One, in regards to both intended use and technology characteristics. Both devices function as aids to the diagnosis of sleep-related breathing disorders. The WatchPAT One is composed of skin-mounted sensors located on the finger, wrist, and chest. The WatchPAT chest sensor measures snoring, body position, and chest movements. The ANNE Chest Sensor collects similar data as the WatchPAT chest sensor, with the addition of ECG-derived heart rate. Both the ANNE Limb Sensor and WatchPAT finger sensor collect a PPG signal for PAT and SpO_2 measurements. Performance of both devices were validated in clinical studies against PSG and in testing according to the same recognized consensus standards.

X. Conclusion

The results of the substantial equivalence assessment, taken together with the clinical and performance testing data, demonstrate that ANNE Sleep's performance characteristics are substantially equivalent to the predicate devices in both technology and intended use.