August 10, 2023

Sibel Health Inc.
Sarah Coughlin
Senior Regulatory Affairs and Quality Assurance Engineer
6650 W Touhy Ave.
Niles, Illinois 60714

Re: K223711
Trade/Device Name: ANNE One
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, MWI, FLL, DQA, MWJ, KMI
Dated: July 6, 2023
Received: July 10, 2023

Dear Sarah Coughlin:

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,

Jennifer W. Shih -S

Jennifer Shih Kozen
Assistant Director
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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)*
K223711

Device Name
ANNE One

Indications for Use *(Describe)*
ANNE One is a wireless monitoring platform indicated for the measurement of electrocardiography (ECG) waveforms, heart rate, respiratory rate, functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, activity, body position, fall detection, skin temperature, and body temperature by qualified healthcare professionals in home and healthcare settings. ANNE One is compatible with third-party, FDA-cleared devices for noninvasive blood pressure, SpO2, pulse rate, and body temperature measurements. The device is indicated for monitoring ECG waveforms and heart rate on ambulatory patients. The device is not intended to monitor or measure respiratory rate, SpO2, pulse rate, or noninvasive blood pressure while the patient undergoes significant motion or is active.

ANNE One continuously monitors the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system provides visual notification when the patient's position has not changed from a preset threshold of time.

The device is intended for use on general care patients who are 12 years of age or older as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment. The data from ANNE One are transmitted wirelessly for display, storage, and analysis. The device is not intended for use on critical care patients.

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

I. Submitter:

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Official Correspondent:
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Tel: (224) 251-8859

Date Prepared: 08/10/2023

II. Device Information

Name of Device: ANNE One

510K Number: K223711

Classification Name: Radiofrequency Physiological Signal Transmitter and Receiver

Regulation: 21 CFR §870.2910

Regulatory Class: Class II

Product Classification Code: DRG, MWI, FLL, DQA, MWJ, KMI

III. Predicate Device

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

IV. Reference Devices

Trade Name: ANNE Sleep
510(k): K220095
Device Manufacturer: Sibel Health Inc.

Trade Name: BioSticker System
510(k): K191614
Device Manufacturer: BioIntelliSense Inc.

Trade Name: Leaf Patient Monitoring System
510(k): K141877
Device Manufacturer: Leaf Healthcare Incorporated

Trade Name: Eclipse Mini
510(k): K212317
Device Manufacturer: Spacelabs

V. Device Description

ANNE One is a wireless monitoring platform that streams and stores real-time biosignals including electrocardiography (ECG), photoplethysmography (PPG), 3-axis accelerometry, and temperature to measure vital signs such as heart rate, respiratory rate, SpO_2, pulse rate, skin temperature, and body temperature. The ECG signal is not intended for automated arrhythmia detection or classification; rather it is intended for manual interpretation, and the automated computation of heart rate through QRS identification using the well-known Pan-Tompkins beat detection algorithm. The displayed waveform is only intended for display as a check for normal ECG rhythm. The waveform is not intended for manual discrimination of any arrhythmias or cardiac conditions. The system features two skin-mounted, bio-integrated sensors that pair with the ANNE View software application for the continuous display, storage, and analysis of vital sign measurements and physiological waveforms. The system is also compatible with optional FDA-cleared third-party devices for SpO_2, non-invasive blood pressure, and body temperature measurements.

VI. Indications for Use

ANNE One is a wireless monitoring platform indicated for the measurement of electrocardiography (ECG) waveforms, heart rate, respiratory rate, functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, activity, body position, fall detection, skin temperature, and body temperature by qualified healthcare professionals in home and healthcare settings. ANNE One is compatible with third-party, FDA-cleared devices for noninvasive blood pressure, SpO_2, pulse rate, and body temperature measurements. The device is indicated for monitoring ECG waveforms and heart rate on ambulatory patients. The device is not intended to monitor or measure respiratory rate, SpO_2, pulse rate, or noninvasive blood pressure while the patient undergoes significant motion or is active.

ANNE One continuously monitors the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system provides visual notification when the patient's position has not changed from a preset threshold of time.

The device is intended for use on general care patients who are 12 years of age or older as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment. The data from ANNE One are transmitted wirelessly for display, storage, and analysis. The device is not intended for use on critical care patients.

VII. Performance Data

The following consensus standards and bench testing were used to evaluate the substantial equivalence of ANNE One:

- 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 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.
- Safety and performance testing of ECG per IEC 60601-2-27:2011 and IEC 60601-2-47:2012.
- Defibrillation testing according to Section 8.5.5 of ANSI/AAMI ES60601-1:2005/(R)2012
- 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, respiratory rate, pulse rate, skin temperature, body temperature, activity, and posture.
- 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.

VIII. 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.

Respiratory Rate Accuracy: Sibel validated the accuracy of respiratory rate measurements compared to etCO2 in n=40 healthy adult subjects over the output range of 8-30 breaths per

minute. The mean absolute error of respiratory rate measurements with ANNE One was within ±3bpm of the reference device, meeting the defined performance criteria.

IX. Conclusion

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

	Subject device Sibel Health Inc.	**Predicate device Sibel Health Inc.**	**Reference device Sibel Health Inc.**	**Reference device BioIntelliSense Inc.**	**Reference Device Leaf Healthcare, Inc.**	**Reference Device Spacelabs**	**Variances / Equivalence**
Trade Name	ANNE One	ANNE One	ANNE Sleep	BioSticker System	Leaf Patient Monitoring System	Eclipse Mini	
510(k) Number	K223711	K211305	K220095	K191614	K141877	K212317	
Class	II	II	II	II	I	II	**Equivalent**
Product Code	DRG, MWI, FLL, DQA, MWJ, KMI	DRG, MWI, FLL	MNR	DRG	KMI	MWJ	**Similar** The DQA product code for the oximeter is supported by the ANNE Sleep reference device. The MWJ product code for ambulatory ECG monitoring without analysis is supported by safety and performance testing to consensus standards as well as the K212317 reference. The KMI product code for bed-patient monitoring is supported by the Leaf Patient Monitoring System reference device.
Regulati	870.2910	870.2910	868.2375	870.2910	880.2400	870.2800	**Equivalent**

on Number and Regulation Name	Transmitters and Receivers, Physiological Signal, Radiofrequency	Transmitters and Receivers, Physiological Signal, Radiofrequency	Breathing Frequency Monitor	Transmitters and Receivers, Physiological Signal, Radiofrequency	Bed-patient Monitor	Medical magnetic tape recorder	
Indications for Use	ANNE One is a wireless monitoring platform indicated for the measurement of electrocardiography (ECG) waveforms, heart rate, respiratory rate, functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, activity, body position, fall detection, skin temperature, and body temperature by qualified healthcare professionals in home and healthcare settings. ANNE One is compatible with third-party, FDA-cleared devices for noninvasive blood	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	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 BioSticker System is a remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings while the patient is at rest. This can include heart rate, respiratory rate, and skin temperature. Data are transmitted via wireless connection from the BioSticker for storage and analysis. The device is intended for use on general care patients who are 21 years of age or older as a general patient monitor, to provide physiological	The Leaf Patient Monitoring System monitors the orientation and activity of patients susceptible to pressure ulcers. It allows healthcare providers to implement individualized turn management plans and continuously monitor each patient. The Leaf Patient Monitoring System provides alerts when patient orientation or activity deviates from parameters set by healthcare providers. The device is intended for use in medical, nursing, and long-term care facilities, including independent living, assisted-living and rehabilitation facilities.	The Eclipse MINI Model 98900 is a portable non-invasive continuous ambulatory ECG patch recorder intended to record the patient's electrocardiogram. The recorder is intended to be used by either paediatric or adult patients suspected of cardiac arrhythmias in either a clinical setting or at home. The recorder does no cardiac analysis and is used with Spacelabs Ambulatory ECG Analysis Software.	**Similar** The subject device utilizes the same sensors and algorithms for the calculation of SpO_2 and pulse rate as the reference device, ANNE Sleep. The subject device is compatible with an optional, FDA-cleared third-party device for NIBP monitoring. Ambulatory ECG heart rate monitoring is supported by performance testing to consensus standards as well as the K212317 reference device. Monitoring of body position for turn management in patients susceptible to pressure ulcers with the subject device is supported by the Leaf reference device. The differences do

	pressure, SpO_2, pulse rate, and body temperature measurements. The device is indicated for monitoring ECG waveforms and heart rate on ambulatory patients. The device is not intended to monitor or measure respiratory rate, SpO_2, pulse rate, or noninvasive blood pressure while the patient undergoes significant motion or is active. ANNE One continuously monitors the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system provides visual notification when the patient's position has not	device is not intended to monitor or measure respiratory rate or heart rate on ambulatory patients.		information. The data from the BioSticker System are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended to measure physiological parameters while the patient undergoes significant motion or is active. The device is not intended for use on critical care patients.			not affect safety or effectiveness.

	changed from a preset threshold of time. The device is intended for use on general care patients who are 12 years of age or older as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment. The data from ANNE One are transmitted wirelessly for display, storage, and analysis. The device is not intended for use on critical care patients.						
Target Population	12 years of age and older	18 years of age and older	22 years of age and older	21 years of age or older	18 years of age and older	Pediatric and adult	**Similar** The subject device's target population includes adolescents aged 12 to 17. Safety and effectiveness in this population is established through literature. ECG monitoring in the

							target population is supported by the Eclipse Mini reference device. Safety and effectiveness of RR monitoring in the adolescent subpopulation is demonstrated through the extrapolation of adult clinical data.
Use Environment	Home and healthcare settings	Healthcare settings	Recording in the home environment with the report and interpretation performed in the clinical setting.	Home and healthcare settings	Medical, nursing, and long-term care facilities	Clinical and home	**Equivalent**
Sensor Placement	Finger and Chest	Finger and Chest	Finger and Chest	Chest	Chest	Chest	**Equivalent**
Heart Rate	30-300 bpm (the greater of ± 10% or ± 5 bpm)	30 - 270 bpm (the greater of ± 10% or ± 5bpm)	30-300 bpm (the greater of ± 10% or ± 5 bpm)	40-125 bpm (<± 5 beats per minute)	N/A	N/A	**Equivalent**
Respiratory Rate	Accelerometer-derived 8 - 30 bpm (± 3 bpm MAE)	ECG-derived 8 - 35 bpm (± 3 bpm RMSE)	N/A	Accelerometer-derived 10 - 30 bpm (± 3 bpm MAE)	N/A	N/A	**Equivalent** The range and accuracy of RR is supported by the K211305 predicate device and the K191614 reference. The use of accelerometer-derived RR is supported by the K191614 reference device.

Skin Temperature	73.4°F - 109.4°F (±0.54°F) 23°C - 43°C (±0.3°C)	73.4°F - 109.4°F (±0.54°F) 23°C - 43°C (±0.3°C)	N/A	86°F - 107.6°F (30°C - 42°C) < 96.4°F ± 0.5°F (< 35.8°C ± 0.3°C) 96.4°F to 98°F ± 0.3°F (35.8°C to 37°C ± 0.2°C) 98°F to 102°F ± 0.2°F (37°C to 39°C ± 0.1 °C) 102°F to 106°F ± 0.3°F (39°C to 41ºC ± 0.2°C) > 106°F ± 0.5°F (> 41ºC ± 0.3°C)	N/A	N/A	**Equivalent**
Body Temperature	± 0.05 °C (± 0.1 °F) during 35.00 °C ~38.00°C (95.00 °F ~100.40°F) ± 0.1°C (± 0.2 °F) during T<35.00°C (95.00°F) or T>38.00°C (100.40°F)	93.2°F - 109.4°F (±0.54°F) 34°C - 43°C (±0.3°C)	N/A	N/A	N/A	N/A	**Different** The subject device may be used with a third-party, FDA-cleared thermometer for spot-check body temperature.
SpO2	A_{RMS} ≤ 3% (range 70-100%)	N/A	A_{RMS} ≤ 3% (range 70-100%)	N/A	N/A	N/A	**Equivalent**
Pulse Rate	30-300 bpm (the greater of ± 10% or ± 5 bpm)	N/A	30-300 bpm (the greater of ± 10% or ± 5 bpm)	N/A	N/A	N/A	**Equivalent**
Activity	Accelerometer	Accelerometer	Accelerometer	Accelerometer	Accelerometer	N/A	**Equivalent**

Posture	Body Position Fall Detection	Fall Count	Body Position	Body Position	Body Position	N/A	**Equivalent**
Non-Invasive Blood Pressure (NIBP)	0 - 300 mmHg (± 3 mmHg)	N/A	N/A	N/A	N/A	N/A	**Different** The subject device may be used with an FDA cleared BP monitor.
ECG Waveform Display	Compliant to IEC 60601-2-27 Compliant to IEC 60601-2-47	Continuous ECG waveform collection	Continuous ECG waveform collection	N/A	N/A	Compliant to IEC 60601-2-47	**Different** While the K211305 predicate device collects ECG signals, the waveform is not displayed on the application. Safety and effectiveness for the ECG waveform display are established through recognized consensus standards including IEC 60601-2-27 and IEC 60601-2-47 as well as the K212317 reference.
ECG Sampling Frequency	ECG Sampling Frequency: 512 Hz Streaming Frequency: 256 Hz	ECG Sampling Frequency: 512 Hz Streaming Frequency: 256 Hz	ECG Sampling Frequency: 512 Hz Streaming Frequency: 256 Hz	N/A	N/A	Not publicly available	**Equivalent**
ECG Resolution	18 bit	18 bit	18 bit	N/A	N/A	Not publicly available	**Equivalent**

Data	Data is transmitted wirelessly via Bluetooth from the sensors to a mobile device. Data may be downloaded for later storage and analysis.	Data is transmitted wirelessly via Bluetooth from the sensors to a mobile device.	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 is transmitted wirelessly via Bluetooth from the sensor to a mobile device for storage and analysis.	Data is transmitted wirelessly via Leaf Antennas to a monitoring station equipped with a USB RF Transceiver and the Leaf Turn Management Software.	Data is transmitted from the sensor to a computer with a standard USB cable	**Similar** The subject device allows data download to the mobile device. This functionality was verified through testing.
Notification	Provides visual notification on patient orientation.	No notification ability	No notification ability	No notification ability	Provides alerts on patient orientation.	N/A	**Similar** The subject device provides a visual notification on patient orientation.
Motion	Respiratory rate, SpO2, and pulse rate measurements should not be taken during motion. Heart rate and ECG may be taken during motion.	Heart rate and respiratory rate not indicated for use during motion.	Not indicated for use during motion	Not indicated for use during motion	N/A	ECG during motion.	**Similar** Both the subject and predicate devices are not indicated for respiratory rate measurements during motion. The subject and ANNE Sleep reference are not indicated for SpO2 or pulse rate measurements during motion. The ANNE One device is indicated for heart rate measurements during motion. This difference is supported by testing on standard ambulatory

							databases as described in IEC 60601-2-47.
Measurement modality	Continuous Measurements: Respiratory rate, ECG, heart rate, SpO2, pulse rate, skin temperature, body position Spot Check Measurements with third party devices: Blood pressure, body temperature	Continuous Measurements: Respiratory rate, heart rate, skin temperature, body temperature, body position, step count	Continuous measurements: SpO2, pulse rate, heart rate, peripheral arterial tonometry, snore, chest movement, body position	Continuous measurements: Heart rate, respiratory rate, skin temperature	Continuous measurements: Body Position	Continuous measurements: ECG	**Similar** ANNE One and the predicate K211305 display continuous heart rate, respiratory rate, skin temperature, and body position. The ANNE One subject device also streams continuous ECG for display on the ANNE View application. This difference is demonstrated to not influence safety or effectiveness through testing according to consensus standards. The subject device and ANNE Sleep reference include continuous SpO2 and pulse rate measurement from PPG. The ANNE One subject device does not include continuous body temperature measurements, but instead allows users to take spot check measurements with a standard, FDA-cleared

							third-party thermometer. The ANNE One subject device is also compatible with an optional FDA-cleared third part blood pressure monitor for spot check NIBP measurements.
Monitoring Type	Real time monitoring Data storage for later analysis	Real time monitoring	Data storage for later analysis	Real time monitoring	Real time monitoring Data storage for later analysis	Data storage for later analysis	**Equivalent** The subject and predicate devices continuously stream physiological data for display on the ANNE Tablet via Bluetooth. Data is also stored on the sensors in the subject device and can be offloaded to the ANNE Tablet at the end of the monitoring session, similar to the ANNE Sleep reference device. The ability of the device to stream data is not impacted by the storage feature. Both real time streaming and storage for later analysis were verified in software system testing.
Alarms	No alarming capabilities	No alarming capabilities	No alarming capabilities	No alarming capabilities	No alarming capabilities	No alarming capabilities	**Equivalent** ANNE One is

	Visual alerts for turn management.				Visual alerts for turn management.		equivalent to the Leaf Healthcare reference device.
Apnea Claims	Not an apnea monitor	Not an apnea monitor	Not an apnea monitor	Not an apnea monitor	Not an apnea monitor	Not an apnea monitor	**Equivalent**