September 14, 2021

Sibel Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K211305
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
Dated: July 23, 2021
Received: July 27, 2021

Dear Dave Yungvirt:

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 Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211305

Device Name
ANNE One

Indications for Use *(Describe)*
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 heart rate on ambulatory 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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6650 W. Touhy Avenue, Niles, IL 60714
Tel: (224) 251-8859

Date Prepared: 9/7/2021

II. Device Information

Name of Device: ANNE One

510K Number: K211305

Common or Usual Name: Wireless Remote Monitoring System

Classification Name: Radiofrequency Physiological Signal Transmitter and Receiver

Review Panel: Cardiovascular

Regulation: 21 CFR §870.2910

Regulatory Class: Class II

Product Classification Code: DRG, MWI, FLL

III. Predicate Device

Predicate - Trade Name: Patient Status Engine
Predicate 510(k): K172329
Predicate device manufacturer: Isansys Lifecare Ltd

IV. Reference Device

Reference device – Trade Name: Fever Scout Continuous Monitoring thermometer
Reference 510(k): K162137
Reference Manufacturer: VivaInk Inc.

V. Device Description

ANNE One is a wireless multi-parameter vital signs monitoring system that consists of the following components, and subsystems:

A. ANNE Tablet (Samsung Galaxy Tablet) – manufactured by Samsung
B. ANNE View Mobile Application (software) – manufactured by Sibel Inc.

C. ANNE Chest Sensor – manufactured by Sibel Inc.

D. ANNE Limb Sensor – manufactured by Sibel Inc.

E. ANNE Wireless Charger – manufactured by Sibel Inc.

The ANNE Chest Sensor is a battery-operated, skin-mounted sensor with wireless transceiver capabilities worn on the upper body to measure heart rate, respiratory rate, step count, fall count, and skin temperature.

The ANNE Limb Sensor is an additional battery-operated skin-mounted sensor with wireless transceiver capabilities worn on the finger to measure skin temperature. When placed underneath the axillae, the ANNE Limb Sensor can measure body temperature.

Both the ANNE Chest and ANNE Limb Sensors continuously gather vital signs data from the person being monitored and then transmit the encrypted data to the ANNE Tablet operating the ANNE View Mobile Application—a mobile device software application.

VI. Indications for Use

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 heart rate on ambulatory patients.

Table 5-1: Substantial Equivalence for Indication for Use

	Subject device Sibel Inc.	**Predicate device Isansys Lifecare Ltd**	**Variances / Equivalence**
Trade Name	ANNE One	Patient Status Engine	
510(k) Number	K211305	K172329	N/A
Class	II	II	**Equivalent**
Product Code	DRG, MWI, FLL	DRG	**Equivalent**
Regulation Number and Regulation Name	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	**Equivalent**

	Subject device Sibel Inc.	**Predicate device Isansys Lifecare Ltd**	**Variances / Equivalence**
Indications for Use	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 heart rate on ambulatory patients.	The device is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This includes heart rate, heart rate variability (R-R interval), ECG derived respiration rate data (EDR), skin temperature, activity, posture and optional SpO_2 and noninvasive Blood Pressure (BP). Data is transmitted wirelessly from the sensors to the Patient Gateways and from the Patient Gateways to a central Server where it is stored for analysis. The Patient Status Engine can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.	**Similar** ANNE One does not include optional SpO_2 and non-invasive BP measurements. ANNE One does not measure heart rate variability. ANNE One does not include the ability to notify healthcare professionals when physiological data fall outside selected parameters. ANNE One does not store data for future analysis. ANNE One is not intended to monitor or measure respiratory rate or heart rate on ambulatory patients. The differences do not affect safety or effectiveness.
Intended Use	ANNE One 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.	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 physiological information.	**Equivalent**
Use Environment	Healthcare Settings	Home and Healthcare Settings	**Different** ANNE One does not offer Home use. The differences do not affect safety or effectiveness.
Heart Rate	Yes	Yes	**Equivalent**

	Subject device Sibel Inc.	**Predicate device Isansys Lifecare Ltd**	**Variances / Equivalence**
R-R Interval	No	Yes	**Different** ANNE One is not indicated for the display of R-R interval. However, it does calculate the R-R interval to determine HR. This difference does not affect safety or effectiveness.
Respiration Rate	Yes	Yes	**Equivalent** Both the ANNE One and Patient Status Engine derive respiratory rate from ECG alone (EDR).
Skin Temperature	Yes	Yes	**Equivalent**
Body Temperature	Yes on axilla/armpit	Yes*	**Equivalent** The differences do not affect safety or effectiveness.
SpO_2	No	Yes – optional with a FDA cleared SpO_2 oximeter	**Different** Without the optional SpO_2 oximeter, the devices are equivalent. The difference does not affect safety or effectiveness.
Activity	Yes	Yes	**Equivalent** The ANNE One specifically measures activity as step count. The differences do not affect safety or effectiveness.
Posture	Yes	Yes	**Equivalent** The ANNE One specifically measures posture only as it relates to fall count. The differences do not affect safety or effectiveness
Non-Invasive Blood Pressure (NIBP)	No	Yes – optional with a FDA cleared NIBP device	**Different** Without the optional NIBP device, the devices are equivalent. The difference does not affect safety or effectiveness.

	Subject device Sibel Inc.	**Predicate device Isansys Lifecare Ltd**	**Variances / Equivalence**
Data	Data transmitted wirelessly via Bluetooth from sensors to mobile device	Data is transmitted wirelessly via Bluetooth from the sensors to the Patient Gateways and from the Patient Gateways to a central Server where it is stored for analysis.	**Equivalent** ANNE One does not offer data transmission to a central Server or data download. The differences do not affect safety or effectiveness.
Notification	No notification ability	The Patient Status Engine can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.	**Different** ANNE One does not offer a notification but provides a real-time display. This difference does not affect safety of the device. Performance data demonstrates that this change does not affect effectiveness.

*The labeling for the Patient Status Engine states that the LifeTemp Sensor can be used for body temperature measurement if placed under the axilla, but this feature is not included in the device's indications for use.

Validation methods and laboratory accuracy data for body temperature measurements from the Fever Scout reference device were further utilized to demonstrate substantial equivalence to ANNE One.

VII. Performance Data

Verification and Validation tests established the safety and effectiveness of ANNE One. The following performance data have been provided in support of the substantial equivalence determination:

Sterilization & Shelf-life Testing

ANNE One is non-sterile, and therefore sterilization data is not provided. The shelf-life study under accelerated aging data has been provided to support the labeled shelf-life claim for ANNE One. Additional peel force testing established the safety of the ANNE adhesive compared to standard FDA-cleared medical adhesives.

Biocompatibility Testing

Biocompatibility testing was performed for all patient-contacting materials used in ANNE One, and the results indicated that all patient-contacting materials in the ANNE One system are biologically compatible and satisfy the requirements defined in ISO 10993 Part 1, entitled 'Use of International Standard ISO-10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

Electromagnetic Compatibility and Electrical Safety

Electrical safety and electromagnetic compatibility testing were conducted on ANNE One. The device complies with the ANSI/AAMI ES60601-1:2005/(R)2012 and IEC 60601-1-2:2014

standards. The device also complies with the FCC CFR 47 Part 15 Subpart C standards for wireless communication. The device was tested and demonstrated to be safe in case of defibrillation according to Section 8.5.5 of ANSI/AAMI ES60601-1:2005/(R)2012.

Software Verification and Validation Testing

Software verification and validation testing demonstrated the safety and effectiveness of ANNE One. Based on the FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the software level of concern for ANNE One is determined to be *Moderate*.

Benchtop Testing and Simulated Use Testing

Bench testing was performed to verify device specifications and to ensure mechanical and electrical requirements were met. Laboratory accuracy testing according to ISO 80601-2-56:2017 Section 201.101.2 validated the effectiveness of the ANNE Chest and Limb sensor for skin temperature measurements and the Limb Sensor for body temperature measurements when placed under the axillae. Heart rate measurements with ANNE One were verified according to IEC 60601-2-27 Sections 201.12.101.15 and 201.12.1.101.17. A simulated use study validated heart rate measurements in 35 healthy subjects against an FDA-cleared reference device. Respiratory rate measurements with ANNE One were validated in 50 healthy subjects against an FDA-cleared End Tidal Carbon Dioxide ($EtCO_2$) reference device. The step and fall count features were demonstrated to conform to their design specifications through comparison to manual counts.

Simulated use testing validated the measurements of skin temperature, body temperature, step count, and fall detection by the ANNE One system in n=10 subjects. The ANNE Hydrogel adhesive was also assessed for skin adhesion, pain upon removal, irritation, and comfort. The study demonstrated the functionality and accuracy of the system.

Animal Study

Animal testing was not required to demonstrate the safety and effectiveness of ANNE One.

Clinical Study

Clinical testing was not required to demonstrate the safety and effectiveness of ANNE One. Instead, substantial equivalence is supported by Bench and Simulated Use testing.

Usability Testing

Studies related to human factors engineering and ease of use of the ANNE One were conducted in accordance with the principles of IEC 62366, Medical devices – Applications of usability engineering to medical devices and the document entitled Applying Human Factors and Usability Engineering to Medical Devices.

VII. Conclusion

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

It has been shown through the documents provided in this 510(k) submission that the minor differences between ANNE One and the predicate device of Patient Status Engine, as well as the reference device of the Fever Scout Continuous Monitoring thermometer, do not raise any new questions regarding its safety and performance. Any differences between the subject device and the predicate/reference devices have no significant effect on safety or effectiveness as established through performance testing.