June 3, 2024

Sibel Health Inc.
Sarah Coughlin
Regulatory Affairs Manager
2017 N Mendell
Unit 2SE
Chicago, Illinois 60614

Re: K240251
Trade/Device Name: ANNE Chest
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, FLL, MWJ, KMI, BZQ, MWI
Dated: May 10, 2024
Received: May 10, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240251

Device Name

ANNE Chest

Indications for Use *(Describe)*

The ANNE Chest is a wearable, wireless sensor intended for the measurement of electrocardiography (ECG) waveforms, heart rate, respiratory rate, activity, fall detection, body position, and skin temperature. The ANNE Chest sensor is not intended to monitor or measure respiratory rate while the patient undergoes significant motion or is active. The ANNE Chest sensor communicates with compatible software applications for the display, storage, and analysis of data. The device is intended to provide continuous physiological information as an aid to diagnosis and treatment by healthcare professionals in general care patients who are 12 years of age or older in clinical and home environments. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

I. Submitter:

Sibel Health Inc.
2017 N Mendell St. Suite 2SE Chicago, IL 60614
Tel: (224) 251-8859

Official Correspondent:
Sarah Coughlin, Regulatory Affairs Manager
2017 N Mendell St. Suite 2SE Chicago, IL 60614
Tel: (224) 251-8859

Date Prepared: 05/09/2024

II. Device Information

Name of Device: ANNE Chest

510K Number: K240251

Classification Name: Radiofrequency Physiological Signal Transmitter and Receiver

Regulation: 21 CFR §870.2910

Regulatory Class: Class II

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

III. Predicate Device

Primary Predicate
Trade Name: ANNE One
510(k): K223711
Device Manufacturer: Sibel Health Inc.

Secondary Predicate
Trade Name: Portrait Mobile Monitoring Solution
510(k) Number: K230626
Manufacturer: GE Medical Systems Information Technologies, Inc.

IV. Device Description

The ANNE Chest Sensor is a skin-mounted, bio-integrated sensor that collects real-time biosignals including electrocardiography (ECG), 3-axis accelerometry, and temperature to measure vital signs such as heart rate, respiratory rate, body position, fall detection, and skin temperature. The sensor communicates via Bluetooth to the Sibel SDK, which may be integrated within software applications for the display and storage of data. The ECG signal

obtained by the ANNE Chest sensor is not intended for manual discrimination of any arrhythmias or cardiac conditions.

V. Indications for Use

The ANNE Chest is a wearable, wireless sensor intended for the measurement of electrocardiography (ECG) waveforms, heart rate, respiratory rate, activity, fall detection, body position, and skin temperature. The ANNE Chest sensor is not intended to monitor or measure respiratory rate while the patient undergoes significant motion or is active. The ANNE Chest sensor communicates with compatible software applications for the display, storage, and analysis of data. The device is intended to provide continuous physiological information as an aid to diagnosis and treatment by healthcare professionals in general care patients who are 12 years of age or older in clinical and home environments. The device is not intended for use on critical care patients.

VI. Performance Data

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

- Electrical safety and electromagnetic compatibility testing according to ANSI/AAMI ES60601-1:2005/(R) 2020 and IEC 60601-1-2:2014 standards. Electrical safety testing in the home healthcare environment per IEC 60601-1-11:2015.
- Biocompatibility testing according to ISO 10993-5:2009, ISO 10993-10:2021, and ISO 10993-23:2021 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 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, skin temperature, activity, and posture.
- Cybersecurity evaluation according to the FDA guidance document, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

VII. Clinical Studies

Respiratory Rate Accuracy: A clinical validation study was conducted in n=40 healthy adult and adolescent subjects to evaluate respiratory rate measurements with the ANNE Chest sensor against an End Tidal Carbon Dioxide ($EtCO_2$) monitor reference. Testing encompassed a range of patient demographics including age, gender, and BMI. Participants were asked to breathe along with a metronome at 8, 13, 23, 27, and 35 breaths per minute. The test also evaluated respiratory rate at different body positions and before and after motion activities. The mean absolute error (MAE) between the ANNE Chest sensor and capnography was 1.27 breaths per minute.

VIII. Conclusion

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

	Subject device Sibel Health Inc.	**Primary Predicate device Sibel Health Inc.**	**Secondary Predicate GE Medical Systems Information Technologies, Inc.**	**Variances / Equivalence**
Trade Name	ANNE Chest	ANNE One	Portrait Mobile Monitoring Solution	
510(k) Number	K240251	K223711	K230626	
Class	II	II	II	**Equivalent**
Product Code	DRG, FLL, KMI, MWJ, BZQ, MWI	DRG, MWI, FLL, DQA, MWJ, KMI	MHX, MSX, DRG, BZQ, DQA	**Equivalent** BZQ is a product code in the subject device that was not present in the predicate device. However, the predicate device did monitor breathing frequency. The K230626 secondary predicate is used to support the BZQ product code.
Regulation Number and Regulation Name	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	870.1025 Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)	**Equivalent**
Indications for Use	The ANNE Chest is a wearable, wireless sensor intended for the measurement of electrocardiography (ECG) waveforms, heart rate, respiratory rate, activity, fall detection, body position, and skin temperature. The ANNE Chest sensor is not intended to monitor or measure respiratory rate while the patient undergoes significant motion or is active. The ANNE Chest sensor communicates with compatible software applications for the display, storage, and analysis of data. The device is intended to provide continuous physiological information as an aid to diagnosis and treatment	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	Portrait Mobile Monitoring Solution: The Portrait Mobile Monitoring Solution is intended to acquire, store, calculate, display and export patient monitoring data as well as provide real time alarming for monitoring adult and pediatric patients (3 years of age and older, and weighing more than 10 kg). Physiological parameters and waveforms supported are: • Pulse oximetry (SpO2/pulse rate) • Respiration rate (RR) Continuous pulse oximetry and respiration rate monitoring may be used for patients at risk of	**Similar** The subject device utilizes the same ANNE Chest sensor for the monitoring of ECG, heart rate, respiratory rate, body position, activity, and skin temperature as the predicate device ANNE One. The ANNE One predicate has additional outputs including SpO2, pulse rate, body temperature, and non-invasive blood pressure. This difference does not affect safety or effectiveness of the output parameters indicated for use in the subject device.

	by healthcare professionals in general care patients who are 12 years of age or older in clinical and home environments. The device is not intended for use on critical care patients.	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.	cardiorespiratory and infectious complications. The Portrait Mobile Monitoring Solution is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility. This device is not an Apnea monitor (i.e., do not rely on the device for detection or alarm for the cessation of breathing). This device should not be used for life sustaining/supporting purposes. The Portrait Mobile Monitoring Solution is not intended for use in a controlled Magnetic Resonance (MR) environment.	
Target Population	12 years of age and older	12 years of age and older	3 years of age and older, weighing more than 10 kg	**Equivalent**
Use Environment	Home and healthcare settings	Home and healthcare settings	Professional healthcare facility	**Equivalent**
Reprocessing	Multiple patient reusable	Single patient reusable	Semi-disposable	**Different** The subject device is reusable on multiple patients. Validation of the cleaning process and mechanical testing demonstrate that this difference does not impact safety or effectiveness.
Sensor Placement	Chest	Finger and Chest	Portrait Wearable Respiration Rate Sensor and Portrait RR Electrode Patch:	**Equivalent** Placement location of the ANNE Chest sensor is the same between the subject

			Chest	and predicate devices. The predicate device includes an additional sensor, the ANNE Limb Sensor, that is worn on the finger. The ANNE Limb Sensor is not part of the scope of the subject device.
Heart Rate	30 - 270 bpm (the greater of ±10% or ±5bpm)	30-270 bpm (the greater of ± 10% or ± 5 bpm)	N/A	**Equivalent**
Respiratory Rate	Accelerometer and ECG derived 8 - 35 bpm (±3 bpm RMSE)	Accelerometer-derived 8 - 30 bpm (± 3 bpm RMSE)	Derived from impedance and biopotential signals Accuracy range from 4 to 60 breaths/minute (± 3 bpm RMSE)	**Similar** The range for respiratory rate has been extended in the subject device from the K223711 predicate. The range is less than the K230626 secondary predicate. Respiratory rate over the output range for the subject device meets the same accuracy specification as both predicates.
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	**Equivalent**
Body Temperature	Not Applicable	± 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) with use of an optional compatible thermometer	N/A	**Different** The subject device does not have body temperature functionality.
SpO2	Not Applicable	A_{RMS} ≤ 3% (range 70-100%)	A_{RMS} ≤ 2% (range 70-100%) Low perfusion: A_{RMS} ≤ 3% With motion: A_{RMS} ≤ 3%	**Different** The subject device does not have SpO2 functionality.
Pulse Rate	Not Applicable	30-300 bpm (the greater of ± 10% or ± 5 bpm)	30-250 bpm <= 2bpm (30 to 250 bpm) With motion: <=5bpm	**Different** The subject device does not have pulse rate functionality.
Activity	Accelerometer	Accelerometer	N/A	**Equivalent**
Posture	Body Position	Body Position	N/A	**Equivalent**
Non-Invasive Blood Pressure	Not Applicable	0 - 300 mmHg (± 3 mmHg)	N/A	**Not Applicable**

(NIBP)		with use of an optional compatible blood pressure cuff		The subject device does not have NIBP functionality.
ECG Waveform	Compliant to IEC 60601-2-27 Compliant to IEC 60601-2-47	Compliant to IEC 60601-2-27 Compliant to IEC 60601-2-47	N/A	**Equivalent**
ECG Sampling Frequency	ECG Sampling Frequency: 512 Hz Streaming Frequency: 256 Hz	ECG Sampling Frequency: 512 Hz Streaming Frequency: 256 Hz	N/A	**Equivalent**
ECG Resolution	18 bit	18 bit	N/A	**Equivalent**
Data	Data is transmitted wirelessly via Bluetooth from the sensor to the Sibel SDK, which may be integrated within software applications for the display and storage of 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 from the Portrait Sensor Battery to the Portrait Mobile Patient Monitor over a wireless Medical Body Area Network (MBAN) using a proprietary protocol.	**Similar** The subject device allows communication with compatible software applications for the display, storage, and analysis of data.
Notification	No notification ability.	Provides visual notification on patient orientation.	Real time alarming	**Similar** The subject device provides a visual notification on patient orientation.
Motion	Respiratory rate measurements should not be taken during motion. Heart rate and ECG may be taken during motion.	Respiratory rate, SpO2, and pulse rate measurements should not be taken during motion. Heart rate and ECG may be taken during motion.	Ambulatory monitoring	**Equivalent** Equivalent for applicable parameters
Measurement modality	Continuous measurements	Continuous measurements	Continuous measurements	**Equivalent**
Monitoring type	Real time monitoring	Real time monitoring Data storage for later analysis	Real time monitoring	**Equivalent**
Apnea Claims	Not an apnea alarm	Not an apnea alarm	Not an apnea alarm	**Equivalent**