January 8, 2025

Sibel Health Inc.
Peter Xu
Regulatory Affairs Consultant
2017 N Mendell St.
Suite 2SE
Chicago, Illinois 60614

Re: K242842
Trade/Device Name: ANNE View, Central Hub
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, MWI, KMI, DRG
Dated: December 9, 2024
Received: December 9, 2024

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 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)*

K242842

Device Name

ANNE View, Central Hub

Indications for Use *(Describe)*

The ANNE View application is intended for the display of physiological data from the ANNE Chest and ANNE Limb devices. The application is also compatible with third-party, FDA-cleared devices for the display of noninvasive blood pressure, SpO2, pulse rate, and body temperature measurements. The ANNE View application notifies healthcare professionals when physiological data fall outside selected parameters. The ANNE View application displays the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system notifies the user when the patient's position has not changed for a preset threshold of time. The ANNE View application communicates to compatible central monitoring platforms, including the Central Hub, for the display and storage of multiple patients' physiological data. The Central Hub has the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The ANNE View and Central Hub are intended for use by trained, qualified healthcare professionals in the clinical or home healthcare environment. 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.
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Tel: (224) 251-8859

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

Date Prepared: 12/06/2024

II. Device Information

Name of Device: ANNE View, Central Hub

510K Number: K242842

Classification Name: Cardiac monitor (including cardiotachometer and rate alarm)

Regulation: 21 CFR §870.2300

Regulatory Class: Class II

Product Classification Code: MSX, MWI, KMI, DRG

III. Predicate Device

Primary Predicate

Trade Name: Aulisa Multiple Patient Digital Vital Sign Monitoring System MP1000
510(k): K202497
Device Manufacturer: Taiwan Aulisa Medical Devices Technologies Inc.

Secondary Predicate

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

IV. Device Description

The ANNE View application is a bedside patient monitoring device that receives vital signs and physiological data from compatible devices for display and transmission to the Central Hub. The ANNE View application operates on the ANNE Tablet. When connected to the ANNE Chest Sensor, the ANNE View application displays electrocardiography (ECG), skin temperature, heart rate, respiratory rate, and body position data. When connected to the ANNE Limb Sensor, the ANNE View application displays photoplethysmography (PPG), SpO2, pulse rate, and skin temperature data. The ANNE View application is also compatible with optional third-party

devices for SpO2, non-invasive blood pressure, and body temperature measurements. The ANNE View application alarms when physiological data are outside of the configured thresholds.

When the ANNE Tablet is connected to Wi-Fi, the vital signs and physiological data are uploaded from the ANNE View application to the Central Hub. The Central Hub allows healthcare professionals to view vitals data from up to 16 beds on one screen and provides storage of up to 48 hours of data from each patient. Alarm conditions are communicated to the Central Hub from the ANNE View application for visual and audio alarms on the Central Hub.

V. Indications for Use

The ANNE View application is intended for the display of physiological data from the ANNE Chest and ANNE Limb devices. The application is also compatible with third-party, FDA-cleared devices for the display of noninvasive blood pressure, SpO2, pulse rate, and body temperature measurements. The ANNE View application notifies healthcare professionals when physiological data fall outside selected parameters. The ANNE View application displays the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system notifies the user when the patient's position has not changed for a preset threshold of time. The ANNE View application communicates to compatible central monitoring platforms, including the Central Hub, for the display and storage of multiple patients' physiological data. The Central Hub has the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The ANNE View and Central Hub are intended for use by trained, qualified healthcare professionals in the clinical or home healthcare environment. 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 safety and effectiveness of ANNE View, Central Hub as compared to the predicate:

- Electromagnetic compatibility testing according to IEC 60601-1-2:2020.
- 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.
- Verification of the ECG waveform display per IEC 60601-2-27:2011 and IEC 60601-2-47:2012.
- Usability testing in accordance with the FDA guidance document, Applying Human Factors and Usability Engineering to Medical Devices and IEC 62366-1:2020.
- Cybersecurity evaluation according to the FDA guidance document, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Verification of the alarm system to IEC 60601-1-8:2020.
- Performance evaluation of the HL7 FHIR and IEEE 11073 SDC communication.

VII. Conclusion

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

	Subject Device Sibel Health Inc.	**Primary Predicate Device Taiwan Aulisa Medical Devices Technologies Inc.**	**Secondary Predicate Device Sibel Health Inc**	**Variances / Equivalences**
Trade Name	ANNE View, Central Hub	Aulisa Multiple Patient Digital Vital Sign Monitoring System MP1000	ANNE One	
510(k) Number	K242842	K202497	K223711	
Class	II	II	II	**Equivalent**
Product Code	MSX, MWI, KMI	MSX, MWI	DRG, MWI, FLL, DQA, MWJ, KMI	**Equivalent**
Regulation Number and Name	870.2300 Cardiac monitor (including cardiotachometer and rate alarm)	870.2300 Cardiac monitor (including cardiotachometer and rate alarm)	870.2910 Radiofrequency physiological signal transmitter and receiver	**Equivalent**
Indications for Use	The ANNE View application is intended for the display of physiological data from the ANNE Chest and ANNE Limb devices. The application is also compatible with third-party, FDA-cleared devices for the display of noninvasive blood pressure, SpO2, pulse rate, and body temperature measurements. The ANNE View application notifies healthcare professionals when physiological data fall outside selected parameters. The	The Aulisa Multiple Patient Digital Vital Sign Monitoring System, MP1000, is intended to provide remote central monitoring and display of information as recorded by multiple Aulisa single-patient monitoring systems, on a central remote screen. The system can be used in a hospital type and clinic environment.	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 ,	**Equivalent** Both devices are intended to display real-time physiological data for patient monitoring by healthcare professionals.

	ANNE View application displays the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system notifies the user when the patient's position has not changed for a preset threshold of time. The ANNE View application communicates to compatible central monitoring platforms, including the Central Hub, for the display and storage of multiple patients' physiological data. The Central Hub has the ability to notify healthcare professionals when physiological data fall outside selected parameters. The ANNE View and Central Hub are intended for use by trained, qualified healthcare professionals in the clinical or home healthcare environment. The device is not intended for use on critical care patients.		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.	
Environment of Use	Home and healthcare settings	Hospitals or hospital type and clinic environment	Home and healthcare settings	**Equivalent** The subject device and K223711 predicate are both intended for use in home and healthcare settings. Regardless of environment, all

				three devices are intended to be used solely by healthcare professionals.
Alarms	Visual and auditory alarms	Visual and auditory alarms	No alarming	**Equivalent**
Operating System	ANNE View - Android 14.0 Central Hub Desktop - Windows 11	Windows 10	ANNE View - Android 8.0 or above	**Equivalent**
Communication Method	The ANNE View application communicates with compatible medical devices over Bluetooth. The Central Hub receives data from ANNE View over LAN or WLAN.	LAN and WLAN	The ANNE View application communicates with compatible medical devices over Bluetooth.	**Equivalent**
Monitoring type	The ANNE View application provides real time monitoring. The Central Hub provides real time monitoring and data storage for later analysis.	Real time monitoring and data storage.	The ANNE View application provides real time monitoring and data storage for later analysis.	**Equivalent**
Interoperability	The ANNE View application is interoperable with the ANNE Chest Sensor and the ANNE Limb Sensor. The ANNE View application is also interoperable with third party compatible devices for non-invasive blood pressure, SpO2, pulse rate, and body temperature monitoring. The ANNE View application is interoperable with central monitoring platforms including the Central Hub.	The Aulisa Multiple Patient Digital Vital Sign Monitoring System is interoperable with Aulisa single-patient monitoring systems.	The ANNE View application is interoperable with the ANNE Chest Sensor and the ANNE Limb Sensor. The ANNE View application is also interoperable with third party compatible devices for non-invasive blood pressure, SpO2, pulse rate, and body temperature monitoring.	**Equivalent**