May 28, 2024

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

Re: K240305
Trade/Device Name: ANNE Limb
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, FLL
Dated: May 7, 2024
Received: May 7, 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)*

K240305

Device Name

ANNE Limb

Indications for Use *(Describe)*

The ANNE Limb Sensor is a pulse oximeter intended for continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature. The ANNE Limb Sensor is not intended to monitor or measure SpO2 or pulse rate while the patient undergoes significant motion or is active. The ANNE Limb Sensor communicates with compatible software applications for the display, storage, and analysis of data. The device is indicated for use 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.

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: 04/26/2024

II. Device Information

Name of Device: ANNE Limb

510K Number: K240305

Classification Name: Oximeter

Regulation: 21 CFR §870.2700

Regulatory Class: Class II

Product Classification Code: DQA, FLL

III. Predicate Device

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

IV. Device Description

The ANNE Limb sensor is a wearable, bio-integrated sensor that collects real-time biosignals including photoplethysmography (PPG) and temperature. The ANNE Limb sensor has on-device processing of raw data for the calculation of SpO2 and pulse rate. The sensor communicates via Bluetooth to the Sibel SDK, which may be integrated within software applications for the display and storage of data.

V. Indications for Use

The ANNE Limb Sensor is a pulse oximeter intended for continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature. The ANNE

Limb Sensor is not intended to monitor or measure SpO2 or pulse rate while the patient undergoes significant motion or is active. The ANNE Limb Sensor communicates with compatible software applications for the display, storage, and analysis of data. The device is indicated for use 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 safety and performance of ANNE Limb:

- Electrical safety and electromagnetic compatibility testing according to ANSI/AAMI ES60601-1:2005/(R)2012 and IEC 60601-1-2 Edition 4.0 2014 standards. Electrical safety testing in the home healthcare environment per IEC 60601-1-11:2015.
- Biocompatibility testing according to 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.
- Shelf life testing of the adhesive to demonstrate safety and 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 pulse rate and skin temperature.
- Cybersecurity evaluation according to the FDA guidance document, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

VII. Clinical Studies

SpO2 Accuracy: Sibel validated the accuracy of SpO2 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 (ARMS) was 2.31%, meeting the requirements of the above-mentioned standard.

VIII. Conclusion

The results of the substantial equivalence assessment, taken together with safety and performance testing data, demonstrate that ANNE Limb'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.**	**Variances / Equivalence**
Trade Name	ANNE Limb	ANNE One	
510(k) Number		K223711	
Class	II	II	**Equivalent**
Product Code	DQA, FLL	DRG, DQA, FLL, KMI, MWI, MWJ	**Similar** The MWJ, MWI, KMI, and DRG product codes represent functionalities supported by the ANNE One predicate device that are not part of the intended use of the subject device. Both devices share the DQA and FLL product codes.
Regulation Number and Regulation Name	870.2700 Oximeter	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	**Different** The primary product codes are different. The predicate device also has the DQA product code for oximetry.
Indications for Use	The ANNE Limb Sensor is a pulse oximeter intended for continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature. The ANNE Limb Sensor is not intended to monitor or measure SpO2 or pulse rate while the patient undergoes significant motion or is active. The ANNE Limb Sensor communicates with compatible software applications for the display, storage, and analysis of data. The device is indicated for use 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	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	**Similar** The subject device utilizes the same sensor and algorithms for the calculation of SpO2, pulse rate, and skin temperature as the Limb Sensor of the predicate device, ANNE One. The ANNE One predicate had additional outputs including ECG, heart rate, respiratory rate, and body position. This difference does not affect the substantial equivalence of the output parameters indicated for use in the subject device.

	home environments. The device is not intended for use on critical care patients.	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.	
Target Population	12 years of age and older	12 years of age and older	**Equivalent**
Use Environment	Home and healthcare settings	Home and healthcare settings	**Equivalent**
Reprocessing	Reusable on multiple patients.	Reusable on a single patient.	**Similar** The subject device is reusable on multiple patients. Validation of the cleaning process and mechanical testing demonstrate that this difference does not impact substantial equivalence.
Sensor Placement	Finger	Finger and Chest	**Similar** Placement of the ANNE Limb sensor on the finger is the same between the subject and predicate devices. The predicate device includes an additional sensor, the ANNE Chest Sensor, that is worn on the chest. The ANNE Chest sensor is not part of the scope

			of the subject device.
Heart Rate	Not Applicable	30-270 bpm (the greater of ± 10% or ± 5 bpm)	Not Applicable
Respiratory Rate	Not Applicable	Accelerometer-derived 8 - 30 bpm (± 3 bpm RMSE)	Not Applicable
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)	**Equivalent**
SpO2	A_{RMS} ≤ 3% (range 70-100%)	A_{RMS} ≤ 3% (range 70-100%)	**Equivalent**
Pulse Rate	30-300 bpm (±3 bpm RMSE)	30-300 bpm (±3 bpm RMSE)	**Equivalent**
Activity	Not Applicable	Accelerometer	Not Applicable
Posture	Not Applicable	Body Position Fall Detection	Not Applicable
Non-Invasive Blood Pressure (NIBP)	Not Applicable	0 - 300 mmHg (± 3 mmHg)	Not Applicable
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.	**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.	**Similar** The subject device provides a visual notification on patient orientation.