November 22, 2022

Sibel Inc.
Sarah Coughlin
QARA Engineer
6650 W. Touhy Ave.
Niles, Illinois 60714

Re: K221530
Trade/Device Name: ANNE Pediatric
Regulation Number: 21 CFR 870.29870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG, MWI, FLL
Dated: May 23, 2022
Received: May 26, 2022

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
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)*

K221530

Device Name
ANNE Pediatric

Indications for Use *(Describe)*

ANNE Pediatric is a wireless vital signs and physiological data monitoring platform indicated for the measurement of heart rate, skin temperature, and body temperature by qualified healthcare professionals in healthcare settings. The device is intended for use on neonatal patients of any gestational age up to infants 2 years of age as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment. The device is not intended to monitor critically ill patients. The device is not intended to monitor or measure heart rate during motion. The device is not an apnea alarm.

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 Inc.
6650 W. Touhy Avenue, Niles, IL 60714
Tel: (224) 251-8859

Official Correspondent:
Sarah Coughlin, Senior Regulatory Affairs and Quality Assurance Engineer
6650 W. Touhy Avenue, Niles, IL 60714
Tel: (224) 251-8859

Date Prepared: 10/7/2022

II. Device Information

Name of Device: ANNE Pediatric

510(k) Number: K221530

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

Trade Name: ANNE One
Predicate 510(k): K211305
Predicate device manufacturer: Sibel Inc.

IV. Device Description

ANNE Pediatric is a wireless vital signs and physiological data monitoring platform that collects electrocardiography (ECG) and temperature biosignals to measure vital signs such as heart rate (HR), skin temperature, and body temperature. The system features two skin-mounted, bio-integrated sensors that pair with the ANNE View application for the display of real-time vital measurements. Data is transmitted wirelessly from the sensors via Bluetooth to the mobile device.

V. Indications for Use

ANNE Pediatric is a wireless vital signs and physiological data monitoring platform indicated for the measurement of heart rate, skin temperature, and body temperature by qualified healthcare professionals in healthcare settings. The device is intended for use on neonatal patients of any gestational age up to infants 2 years of age as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment. The device is not intended to monitor critically ill patients. The device is not intended to monitor or measure heart rate during motion. The device is not an apnea alarm.

	Subject device ANNE Pediatric	**Predicate device Sibel Inc.**	**Variances/Equivalence**
Trade Name	ANNE Pediatric	ANNE One	
Class	II	II	**Equivalent**
Product Code	DRG, MWI, FLL	DRG, MWI, FLL	**Equivalent**
Regulation Number and Name	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	**Equivalent**
Indications for Use	ANNE Pediatric is a wireless vital signs and physiological data monitoring platform indicated for the measurement of heart rate, skin temperature, and body temperature by qualified healthcare professionals in healthcare settings. The device is intended for use on neonatal patients of any gestational age up to infants 2 years of age as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment. The device is not intended to monitor critically ill patients. The device is not intended to monitor or measure heart rate during motion. The device is not an apnea alarm.	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.	**Substantially Equivalent**

Target Population	Neonates and infants up to 2 years of age	Adults, 18 years of age and older	**Different**
Use Environment	Healthcare Settings	Healthcare Settings	**Equivalent**
Sensor Placement	Chest and Foot	Chest and Finger	**Substantially Equivalent**
Data	Data transmitted wirelessly via Bluetooth from sensors to mobile device	Data transmitted wirelessly via Bluetooth from sensors to mobile device	**Equivalent**
Notification	No notification ability	No notification ability	**Equivalent**
Heart Rate	Yes	Yes	**Equivalent**
Skin Temperature	Yes	Yes	**Equivalent**
Body Temperature	Yes	Yes	**Equivalent**
Respiratory Rate	No	Yes	**Different**
Step Count	No	Yes	**Different**
Fall Count	No	Yes	**Different**

VI. Clinical Data

The functionality and performance of the ANNE Pediatric system was assessed in n=137 neonates at Aga Khan University, a tertiary healthcare facility in Nairobi, Kenya. The study compared the performance of HR measurements with ANNE Pediatric against the Masimo Rad-97 in one open label and three closed-label rounds with n=70 neonates. Median gestational age of neonates included in HR analysis was 38 (range 25 to 42) weeks. The HR analysis cohort was 44.7% female, 52.9% male, and 1.4% intersex. The normalized root mean square deviation (RMSD) in the final closed-label round of testing with n=20 neonates was 1.2%, meeting the accuracy requirement of ±10% or ±5bpm, whichever is greater, defined in IEC 60601-2-27. No adverse events or skin injuries were reported during the study.

VII. Performance Data

The following consensus standards and bench testing were used to evaluate the safety and effectiveness of ANNE Pediatric:

- Electrical safety and electromagnetic compatibility testing according to ANSI/AAMI ES60601-1:2005/(R)2012 and IEC 60601-1-2:2014 standards.
- 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.
- Defibrillation testing according to Section 8.5.5 of ANSI/AAMI ES60601-1:2005/(R)2012

- 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.
- 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 body temperature measurements according to ISO 80601-2-56:2017.
- Performance testing of heart rate measurements according to Sections 201.12.1.101.15 and 201.12.1.101.17 of IEC 60601-2-27:2011.
- 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. Conclusion

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