February 26, 2026

Sibel Health Inc.
Kevin Dwyer
Director of Quality and Regulatory Affairs
2017 N. Mendell St.
Chicago, Illinois 60614

Re: K253021
Trade/Device Name: ANNE Maternal
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal Monitoring System and accessories
Regulatory Class: II
Product Code: HGM
Dated: September 19, 2025
Received: January 27, 2026

Dear Kevin Dwyer:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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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)*
K253021

Device Name
ANNE Maternal

Indications for Use *(Describe)*
The ANNE® Maternal system is a perinatal monitoring platform intended for the continuous collection, display, and storage of physiological data and vital signs from compatible medical devices in clinical settings. The system supports data acquisition from sensors, clinician inputted data, and compatible software for maternal and fetal monitoring in singleton pregnancies. Examples of parameters include maternal vital signs (e.g. heart rate, respiratory rate, SpO2, blood pressure, temperature), fetal heart rate, and uterine contractions. The system provides both visual and audio alarms, alerts, and notifications at the bedside via a mobile device or a compatible central monitor. The ANNE® Maternal system is intended for use by qualified healthcare professionals. This device is intended for use by healthcare professionals to support clinical decision-making. All information provided by the system is intended to supplement, not replace, the judgement of medical professionals and is not intended to be the sole source of information for decision-making.

The physiological parameters collected by the ANNE® Maternal system is inputted into the integrated electronic Modified Early Obstetric Warning System (MEOWS) tool, which provides information that can signal the need for prompt bedside evaluation by the health care provider. This information is intended as adjunctive information only and is not intended to replace or supersede the review of individual vital signs by qualified healthcare professionals.

This information is intended to supplement, and not replace, the judgment of medical professionals and is not intended to be the sole source of information for decision-making.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary – K253021
# ANNE Maternal

## I. Submitter

Sibel Health

2017 N Mendell St. Suite 2SE

Chicago, IL 60614

Tel: (224) 251-8859

Official Correspondent: Kevin Dwyer, Director of QA/RA

Tel: (224) 251-8859

Date Prepared: 2/25/2026

## II. Device Information

Device Name/Trade Name: ANNE Maternal

Regulation Name: Perinatal monitoring system and accessories.

Regulation Number: 21 CFR §884.2740

Product Classification Code: HGM (System, Monitoring, Perinatal)

Additional Product Classification Codes: MSX, MWI, KMI, DRG

Regulatory Class: Class II

## III. Predicate Device

Trade Name: Sonicaid Team3

510(k) Number: K250777

Device Manufacturer: Huntleigh Healthcare Ltd

The predicate device has not been subject to a design-related recall.

## IV. Device Description

ANNE® Maternal software application is a perinatal monitoring platform that collects, displays, and

stores physiological data from compatible devices for noninvasive blood pressure, $SpO_2$, pulse rate, body temperature, fetal heart rate, and uterine activity.

Designed for use in clinical environments, including labor, delivery, and postpartum care, the platform operates with compatible software display systems such as ANNE® View and Central Hub. ANNE® Maternal integrates physiological parameters into early warning information, When connected to Wi-Fi, data is transmitted and stored to the Central Hub. The system provides both visual and audio alarms, alerts, and notifications. All vital signs are continuously displayed to the clinician, with all clinical decisions remaining the responsibility of the healthcare professional. ANNE® Maternal is intended for use exclusively by trained healthcare professionals following the Instructions for Use.

## V. Indications for Use

The ANNE® Maternal system is a perinatal monitoring platform intended for the continuous collection, display, and storage of physiological data and vital signs from compatible medical devices in clinical settings. The system supports data acquisition from sensors, clinician inputted data, and compatible software for maternal and fetal monitoring in singleton pregnancies. Examples of parameters include maternal vital signs (e.g. heart rate, respiratory rate, SpO2, blood pressure, temperature), fetal heart rate, and uterine contractions. The system provides both visual and audio alarms, alerts, and notifications at the bedside via a mobile device or a compatible central monitor. The ANNE® Maternal system is intended for use by qualified healthcare professionals. This device is intended for use by healthcare professionals to support clinical decision-making. All information provided by the system is intended to supplement, not replace, the judgement of medical professionals and is not intended to be the sole source of information for decision-making.

The physiological parameters collected by the ANNE® Maternal system is inputted into the integrated electronic Modified Early Obstetric Warning System (MEOWS) tool, which provides information that can signal the need for prompt bedside evaluation by the health care provider. This information is intended as adjunctive information only and is not intended to replace or supersede the review of individual vital signs by qualified healthcare professionals.

This information is intended to supplement, and not replace, the judgment of medical professionals and is not intended to be the sole source of information for decision-making.

## VI. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

| | Subject Device Sibel Health Inc. | Primary Predicate:<br>Huntleigh Healthcare Ltd |
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| Trade Name | ANNE Maternal | Sonicaid Team3 |
| 510(k) | K253021 | K250777 |
| Class | II | II |
| Product Code | HGM, MSX, MWI, KMI, DRG | HGM, HEL, HGP, HFM, KXO, DRT, DQA, DXN |
| Regulation Number and Name | 21 CFR 884.274<br><br>Perinatal monitoring system and accessories | 21 CFR 884.274<br><br>Perinatal monitoring system and accessories |
| Indications for Use | The ANNE® Maternal system is a perinatal monitoring platform intended for the continuous collection, display, and storage of physiological data and vital signs from compatible medical devices in clinical settings. The system supports data acquisition from sensors, clinician inputted data, and compatible software for maternal and fetal monitoring in singleton pregnancies. Examples of parameters include maternal vital signs (e.g. heart rate, respiratory rate, SpO2, blood pressure, temperature), fetal heart rate, and uterine contractions. The system provides both visual and audio alarms, alerts, and notifications at the bedside via a mobile device or a compatible central monitor. The ANNE® Maternal system is intended for use by qualified healthcare professionals. This device is intended for use by healthcare professionals to support clinical decision-making. All information provided by the system is intended to supplement, not replace, the judgement of medical professionals and is not intended to be the sole source of information for decision-making.<br><br>The physiological parameters collected by the ANNE® Maternal system is inputted into the integrated electronic Modified | The Team3 fetal monitors are indicated for use by trained healthcare professionals in noninvasive and invasive monitoring of physiological parameters in pregnant women and fetuses, during the antepartum and intrapartum periods of pregnancy. The Team3 fetal monitors are intended for pregnant women with singleton or twin pregnancies from the 28th week of gestation, through to term and delivery. In cases of triplet, the Team3 fetal monitors are intended for use from 30th week of gestation through 35 weeks gestation. The devices are intended for use in clinical and hospital-type facilities. Sonicaid Team3 Antepartum is suitable for use when there is a need to monitor the following physiological applications:<br><br>• Single, twin or triplet fetal heart rates by means of ultrasound<br><br>• Uterine activity - externally sensed<br><br>• Manual fetal movement detection - maternally identified using the event marker<br><br>• Automatic fetal movement detection (defaults to OFF / Not for use in twin or triplet pregnancies)<br><br>• Maternal heart rate and oxygen saturation via pulse oximetry |

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| | Early Obstetric Warning System (MEOWS) tool, which provides information that can signal the need for prompt bedside evaluation by the health care provider. This information is intended as adjunctive information only and is not intended to replace or supersede the review of individual vital signs by qualified healthcare professionals. | • Maternal non-invasive blood pressure<br>• The Dawes-Redman Cardiotocography (CTG) analysis output - advises whether a number of defined criteria indicative of a normal cardiotocograph record has been met for singleton pregnancies but not for triplet pregnancies. It provides nonspecific analysis in twin pregnancies due to nonspecific fetal movement input.<br>Sonicaid Team3 Intrapartum is suitable for use when there is a need to monitor the following physiological applications:<br>•Single, twin or triplet fetal heart rates by means of ultrasound and/or FECG •Manual fetal movement detection - maternally identified using the event marker •Maternal heart rate via ECG electrodes •Uterine activity - externally or internally sensed •Maternal heart rate and oxygen saturation via pulse oximetry •Maternal non-invasive blood pressure |
| Includes Alarms | Yes | Yes |
| Algorithms | Yes | Yes |
| Clinical Decision Making Support Features | Yes | Yes |
| Intended Users | Healthcare professionals | Healthcare professionals |
| Target Population | Pregnant persons, single fetus >32 weeks | Pregnant persons, antepartum or intrapartum, >28 weeks gestation |
| Use Environment | Healthcare settings | Healthcare settings |
| Data collection | Collects Fetal Heart Rate (FHR) and Uterine Activity (UA) from third-party devices. | Collects Fetal Heart Rate and Uterine Activity (UA) from associated parts of the Team3 Fetal Monitor. |
| Annotations | Yes | Yes |
| Central Display | Yes | Yes |
| ECG Parameters | Displays ECG waveform collected from compatible FDA 510(k)- | Displays ECG waveform collected from associated parts of the Team3 |

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| | cleared devices, including ANNE Chest and compatible fetal sensors. | monitor system. |

The ANNE® Maternal system shares the same general intended use and fundamental technological purpose as the predicate device (Sonicaid Team3, K250777). Both devices are intended for use by qualified healthcare professionals in clinical settings, including labor, delivery, and postpartum care, for the continuous acquisition, display, and management of maternal and fetal physiological data to support clinical decision-making.

From a technological perspective, both systems collect physiological parameters (e.g., maternal vital signs, fetal heart rate, uterine activity) from compatible monitoring devices, provide visual and audible alarms, and display information at the bedside and/or central monitoring stations. The subject device functions as a data aggregation and display platform that collates and presents physiological measurements without altering the underlying clinical meaning of the acquired parameters.

The primary technological distinction is the incorporation of an integrated electronic Modified Early Obstetric Warning System (MEOWS) within the ANNE® Maternal system. This feature provides information that can signal the need for prompt bedside evaluation by health care providers, based on collected physiological parameters to prompt clinician review. The inclusion of this decision-support functionality does not change the intended use of the device, does not replace clinician judgment, and does not alter the fundamental monitoring function. Rather, it represents an adjunctive software-based early warning notification system similar to other legally marketed perinatal monitoring systems that incorporate algorithm-based decision-support features. As such, this distinction does not raise different questions of safety and effectiveness.

## VII. Non-Clinical Performance Data

The following consensus standards and bench testing were used to evaluate the safety and effectiveness of ANNE Maternal as compared to the predicate device:

- General requirements for basic safety and essential performance testing according to IEC 60601-1
- Electromagnetic compatibility testing according to IEC 60601-1-2:2020.
- Basic safety and essential performance of electrocardiographic monitoring equipment with reference to 60601-2-27.
- Verification of the ECG waveform display per IEC 60601-2-27:2011
- and IEC 60601-2-47:2012.
- Verification of the alarm system to IEC 60601-1-8:2020.
- Basic safety and essential performance testing of pulse oximeter equipment according to ISO 80601-2-61
- Basic safety and essential performance testing of clinical thermometers for body temperature measurement according to ISO 80601-2-56
- Basic safety and essential performance of ultrasonic medical diagnostics and monitoring equipment according to IEC 60601-2-37
- Testing of symbols to be used in labeling according to ISO 15223-1
- Internal benchtop testing to demonstrate mechanical durability and signal accuracy of sensors
- Usability testing performed with reference to IEC 60601-1-6: 2010+AMD1:2013+AMD2:2020 CSV Parts 1-6
- Usability testing performed with reference to the FDA guidance document, Applying Human Factors and Usability Engineering to Medical Devices and IEC 62366-1:2020.
- Software verification and validation testing according to IEC 62304:2015 and the FDA

guidance document, Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff

- Cybersecurity evaluation according to the FDA guidance document, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

## VIII. Clinical Supporting Data

The following sources of data collectively provided clinical supporting data regarding the device integrated Maternal Early Obstetric Warning System (MEOWS) tool.

1. Outside the United States (OUS) clinical validation according to a study by Singh, et. Al.: This was a prospective observational validation study conducted at a single center to evaluate the performance of the Confidential Enquiry into Maternal and Child Health, (CEMACH)-recommended MEOWS chart. The study included a review of 676 obstetric (antepartum, intrapartum and postpartum) admissions. Of these, 200 patients (30%) triggered the MEOWS system, and 86 patients (13%) experienced actual morbidity according to the study's predefined criteria. Results: The MEOWS system demonstrated a sensitivity of 89% with a 95% Confidence Interval (CI) of 81-95% and specificity of 79% with a 95% CI of 76-82% for predicting obstetric morbidity. The positive predictive value was 39% with a 95% CI of 32-46%, while the negative predictive value was 98% with a 95% CI of 96-99%. (Singh S, McGlennan A, England A, Simons R. A validation study of the CEMACH recommended modified early obstetric warning system (MEOWS). Anaesthesia. 2012 Jan;67(1):12-18.)

2. Clinical validation in the US according to study by Arnold, et. Al.: This was a retrospective observational cohort study at a single academic center (University of Chicago) comparing six different early warning tools for predicting clinical deterioration in obstetric patients. The study compared three obstetric-specific tools including MEOWS, two general paper-based tools, and one machine learning-based tool. The study included 19,611 patients hospitalized on obstetric units (antepartum and postpartum) over a 10-year period from November 2008 to December 2018. The study evaluated two primary outcomes: Clinical deterioration (defined as Intensive Care Unit (ICU) transfer and/or death); and New infection.

   **Results**: MEOWS had a discrimination for deterioration, with an AUC of 0.74 ($p < 0.05$) and had the second-best result amongst all 6 early warning tools; but best of the 3 obstetrics-specific tools. (Arnolds DE, Carey KA, Braginsky L, Holt R, Edelson DP, Scavone BM, Churpek M. Comparison of early warning scores for predicting clinical deterioration and infection in obstetric patients. BMC Pregnancy Childbirth. 2022 Apr 6;22(1):295.)

3. OUS Clinical Pilot Study: An observational usability pilot study on 15 subjects confirmed that the subject device functions as intended in displaying the physiological signals and the MEOWS information in an intrapartum obstetrics population.

## IX. Conclusion

The results of the performance testing described above demonstrate that ANNE Maternal is as safe and effective as the predicate device and supports a determination of substantial equivalence.