September 19, 2025

Huntleigh Healthcare Ltd.
Steve Monks
QRE Director
35 Portmanmoor Road
Cardiff, CF24 5HN
UNITED KINGDOM

Re: K250777
Trade/Device Name: Sonicaid Team3
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal Monitoring System and accessories
Regulatory Class: II
Product Code: HGM
Received: August 20, 2025

Dear Steve Monks:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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,

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
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.

510(k) Number *(if known)*
K250777

Device Name
Sonicaid Team3

Indications for Use *(Describe)*
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:

- Single, twin or triplet fetal heart rates by means of ultrasound
- Uterine activity - externally sensed
- Manual fetal movement detection - maternally identified using the event marker
- Automatic fetal movement detection (defaults to OFF / Not for use in twin or triplet pregnancies)
- Maternal heart rate and oxygen saturation via pulse oximetry
- Maternal non-invasive blood pressure
- 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

Sonicaid Team3 Intrapartum is suitable for use when there is a need to monitor the following physiological applications:

- 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

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
Sonicaid Team 3 Fetal Monitor

Name & Address:	Huntleigh Healthcare Limited Unit 35, Portmanmoor Road Cardiff CF24 5HN United Kingdom
Telephone:	+44 (0)2920 485885
Fax:	+44 (0)2920 492520
Prepared:	September 18, 2025
Contact:	Steve Monks

1. Device Information

Device Name:	Sonicaid Team3
Common Name:	Perinatal Monitoring System
Regulation Name:	Perinatal monitoring system and accessories
Regulation Number:	21 CFR 884.2740
Regulatory Class:	II
Product Code:	HGM (system, monitoring, perinatal)
Additional Product Codes:	HEL – Monitor, Heart Rate, Fetal, Ultrasonic HGP – Electrode, Circular (spiral), Scalp and Applicator HFM – Monitor, Uterine Contraction, External (For Use in Clinic) KXO – Monitor, Pressure, Intrauterine DRT – Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm) DQA – Oximeter DXN – System, Measurement, Blood-Pressure, Non-invasive

2. Predicate Device

Predicate Device:	Sonicaid Team3 Fetal Monitor, manufactured by Huntleigh Healthcare Ltd., cleared under K241368

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

3. Device Description

The Sonicaid Team3 is a fetal monitoring device designed for perinatal monitoring. The subject device provides non-invasive and invasive monitoring of physiological parameters in pregnant women and fetuses, including singleton, twin, and triplet fetal heart rate monitoring, during antepartum and intrapartum periods. The subject device includes systems and accessories intended to perform perinatal monitoring as aligned with product code HGM.

The subject device is a modification to the Sonicaid Team3 (K241368) to allow for triplet fetal heart rate monitoring. This modification affects the hardware of the device only. An additional port has been made available on the front of the monitor to allow for a third ultrasound transducer to be connected, so three fetal heart rates can be monitored at once.

All other parameters, materials, software and technology remain identical to the predicate device.

4. Indications for Use

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:

- Single, twin or triplet fetal heart rates by means of ultrasound
- Uterine activity - externally sensed
- Manual fetal movement detection - maternally identified using the event marker
- Automatic fetal movement detection (defaults to OFF / Not for use in twin or triplet pregnancies)
- Maternal heart rate and oxygen saturation via pulse oximetry
- Maternal non-invasive blood pressure
- 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.

Sonicaid Team3 Intrapartum is suitable for use when there is a need to monitor the following physiological applications:

- 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

5. Comparison of Technological Characteristics with Predicate and Device

The following table compares the subject device to the predicate and reference devices with respect to the indications for use and technological characteristics:

Device and Predicate Device(s):	Predicate Device (K241368)	Subject Device
Manufacturer	Huntleigh Healthcare Ltd.	Huntleigh Healthcare Ltd.
Classification	II	II
Product Code	HGM	HGM
Regulation	21 CFR 884.2740	21 CFR 884.2740
Intended Use	System and Accessories intended to perform perinatal monitoring	System and Accessories intended to perform perinatal monitoring
Indications for Use	The Team3 fetal monitors are indicated for use by trained healthcare professionals in non-invasive 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 from the 28th week of gestation, through to term and delivery. 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: • Single or twin fetal heart rates by means of ultrasound • Uterine activity - externally sensed. • Fetal movement – maternally sensed and externally via ultrasound. • Maternal heart rate and oxygen saturation via pulse oximetry • Maternal non-invasive blood pressure • CTG analysis – advises whether a	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: • Single, twin or triplet fetal heart rates by means of ultrasound • Uterine activity - externally sensed • Manual fetal movement detection - maternally identified using the event marker • Automatic fetal movement

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A MEMBER OF THE ARJO FAMILY

	number of defined criteria indicative of a normal cardiotocograph has been met. Sonicaid Team3 Intrapartum is suitable for use when there is a need to monitor the following physiological applications: • Single or twin fetal heart rates by means of ultrasound and/or FECG. • Maternal heart rate via ECG electrodes • Uterine activity – externally or internally sensed • Fetal movement – maternally sensed and externally via ultrasound. • Maternal heart rate and oxygen saturation via pulse oximetry • Maternal non-invasive blood pressure	detection (defaults to OFF / Not for use in twin or triplet pregnancies) • Maternal heart rate and oxygen saturation via pulse oximetry • Maternal non-invasive blood pressure • 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 Sonicaid Team3 Intrapartum is suitable for use when there is a need to monitor the following physiological applications: • 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
Ultrasound	Channels: 2 Mode: Directional Pulsed Doppler FHR Range: 30-240 bpm Frequency 1MHz Safety: Type CF Protection Type: Piezo 8 element I_{spta}: <3mW/cm^2 Material: Novodur P2H-AT	Channels: **3** Mode: Directional Pulsed Doppler FHR Range: 30-240 bpm Frequency 1MHz Safety: Type CF Protection Type: Piezo 8 element I_{spta}: <3mW/cm^2 Material: Novodur P2H-AT
Toco	Type: Tocodynamometer Material: Body – Novodur P2H-AT, Faceplate – Kraiburg TPE TF6 FMA Elastomer	Type: Tocodynamometer Material: Body – Novodur P2H-AT, Faceplate – Kraiburg TPE TF6 FMA Elastomer
Fetal ECG	Channels: 1	Channels: 1

	FHR Range: 30-240 bpm	FHR Range: 30-240 bpm
External Uterine Activity	Channels: 1 Range: 0-100 Relative Units Sensitivity: 100%FSD=120g Offset range: ± 375g Alerts: Toco Persistance Alert	Channels: 1 Range: 0-100 Relative Units Sensitivity: 100%FSD=120g Offset range: ± 375g Alerts: Toco Persistance Alert
Internal Uterine Activity	Channels: 1 Range: 0-100mmHg or 1-13.3kPa Sensitivity: 5µV/V/mmHg	Channels: 1 Range: 0-100mmHg or 1-13.3kPa Sensitivity: 5µV/V/mmHg
Maternal eMHR	Reference: eMHR Channels: 1 Electrode Type: Standard ECG MHR Range: 30-240 bpm	Reference: eMHR Channels: 1 Electrode Type: Standard ECG MHR Range: 30-240 bpm
Maternal Non-Invasive Blood Pressure	Method: Oscillometric OEM: PAR Medizintechnik BP Ranges: Systolic 25-280mmHg, Diastolic 10-220mmHg Pulse Range: 30-240bpm BP Accuracy: ±1.7mmHg Safety Limiters: Over-inflation 300mmHg, Duration 15s	Method: Oscillometric OEM: PAR Medizintechnik BP Ranges: Systolic 25-280mmHg, Diastolic 10-220mmHg Pulse Range: 30-240bpm BP Accuracy: ±1.7mmHg Safety Limiters: Over-inflation 300mmHg, Duration 15s
Maternal Oximetry (MSpO2)	Method: Differential optical transmission Saturation Range: 1-100% $MSpO_2$ Accuracy: 70-100% ±1SD Pulse Range: 30-240 bpm Accuracy: ±3 bpm	Method: Differential optical transmission Saturation Range: 1-100% $MSpO_2$ Accuracy: 70-100% ±1SD Pulse Range: 30-240 bpm Accuracy: ±3 bpm
Dawes Redman Software Analysis	No. of criteria: 'Met or 'Not Met' Measurement Parameters: Signal Loss, Fetal Movements per hour, Basal Heart Rate, Accelerations, Decelerations, High and Low variation episodes, Short term variation Firmware embedded in the Team3 (fetal monitor	No. of criteria: 'Met or 'Not Met' Measurement Parameters: Signal Loss, Fetal Movements per hour, Basal Heart Rate, Accelerations, Decelerations, High and Low variation episodes, Short term variation Firmware embedded in the Team3 (fetal monitor
Patient Event Marker	Channels: 1 Indication: Audio, visual & printed	Channels: 1 Indication: Audio, visual & printed
Display	Type: Colour TFT LCD Size: 17 x 12.8cm (6.7 x 5")	Type: Colour TFT LCD Size: 17 x 12.8cm (6.7 x 5")
Printer	Print Head: 128mm Thick Film Thermal Array Speeds: 1, 2 or 3cm/min, 20cm/min fast forward	Print Head: 128mm Thick Film Thermal Array Speeds: 1, 2 or 3cm/min, 20cm/min fast forward
Controls and Indicators	Power on/off: On/standby touch switch with indicator Audio volume up/down: Volume up/down touch screen 'button'	Power on/off: On/standby touch switch with indicator Audio volume up/down: Volume up/down touch screen 'button'
Interfaces	RS232-CRS: Yes Ethernet – CRS: Yes DVI: 1 channel, DVI-I connector Wireless Telemetry: Yes USB: 2 channels	RS232-CRS: Yes Ethernet – CRS: Yes DVI: 1 channel, DVI-I connector Wireless Telemetry: Yes USB: 2 channels

Physical	Size(WxDxH): 32x23x23.4cm Weight (Net): 6kg	Size(WxDxH): 32x23x23.4cm Weight (Net): 6kg
Mains Power Supply	Voltage: 85-264Vac Frequency: 50 or 60 Hz Consumption (max): <140VA	Voltage: 85-264Vac Frequency: 50 or 60 Hz Consumption (max): <140VA
Internal Battery	Rechargeable 5200mAh Li-ion Battery	Rechargeable 5200mAh Li-ion Battery
Environmental	Operating temp: +10-40°C Storage temp: -20-50°C Operating Press: 70-106kPa Storage Press: 70-106kPa Operating Humidity: 15-90% RH Storage Humidity: 10-90% RH	Operating temp: +10-40°C Storage temp: -20-50°C Operating Press: 70-106kPa Storage Press: 70-106kPa Operating Humidity: 15-90% RH Storage Humidity: 10-90% RH
EMC and Electrical Safety	60601-1-2: Comply 60601-1: Comply	60601-1-2: Comply 60601-1: Comply

The Sonicaid Team3 subject device has the same intended use as the predicate device - a system and accessories intended to perform perinatal monitoring. As noted in the table above, the subject device has identical technological characteristics as the predicate device, except for the inclusion of a third ultrasound transducer port, to allow for triplet fetal heart rate monitoring. This different technological characteristic does not raise different questions of safety and effectiveness and can be addressed through performance testing.

6. Performance Data

Testing Conducted	Discussion
Functional Performance Bench Testing	Performance bench testing was performed on the Sonicaid Team3 device with the incorporation of the new technological characteristic – triplet fetal heart rate monitoring. Ultrasound performance bench testing for triplet heart rate detection was included. Testing demonstrated accurate and simultaneous detection of three independent fetal heart rates across the full operating range (30–240 bpm), with accuracy within ±2 bpm, meeting the predefined acceptance criteria. No concerns were noted. The performance verification, along with the risk analysis confirmed there are no new safety, effectiveness or performance concerns.
Clinical Validation	Clinical validation was assessed via a prospective observational study and carried out by trained healthcare professionals, such as Midwives, in a variety of UK hospital settings and feedback was given. The validation testing was to confirm the device meets the user requirements and functions as intended, with the focus

	of the validation to confirm triplet functionality. In this study of 15 FHR tracings from 8 patients (30–35+6 weeks GA), 100% of evaluators reported correct display and print of fetal heart rates, 100% rated trace quality acceptable, and 93% rated audio performance acceptable, with no major or minor concerns documented. It was concluded that the Sonicaid Team3 meets the intended use and is fit for purpose in regards to the additional feature of monitoring triplets.
EMC	Further EMC testing was conduction on the product with triplet fetal heart rate monitoring functionality option, by a third party laboratory. Testing confirms device complies with EN 60601-1-2:2020

7. Conclusion

The results of the performance testing described above demonstrates that the Sonicaid Team3 is as safe and effective as the predicate device and supports a determination of substantial equivalence.