February 3, 2025

Huntleigh Healthcare Ltd.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K241368
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: October 22, 2024

Dear Prithul Bom:

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.

The FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is

consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241368

Device Name
Sonicaid Team3

Indications for Use *(Describe)*
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 number of defined criteria indicative of a normal cardiograph record 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

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 – K241368
Sonicaid Team 3

Name & Address:	Huntleigh Healthcare Limited Unit 35, Portmanmoor Road Cardiff CF24 5HN United Kingdom
Telephone:	+44 (0)2920 485885
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Prepared:	February 3, 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 K200975

3. Device Description

The Sonicaid Team3, subject device, is a fetal monitoring device designed for perinatal monitoring and includes a software function, the Dawes-Redman CTG Analysis, previously cleared under K992607. The subject device provides non-invasive and invasive monitoring of physiological parameters in pregnant women and fetuses during antepartum and intrapartum periods. The subject device includes systems and

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accessories intended to perform perinatal monitoring as aligned with product code HGM.

Features included in the subject device are the Dawes Redman analysis, used to assess clinically indicated antepartum cardiotocographs (CTGs) in pregnancies from 26 weeks gestation onwards, assisting physicians in identifying normal and non-reassuring traces. The Dawes-Redman software is embedded in the subject device, ensuring integration with the existing hardware. The device is not intended for use in latent or established labor due to the influence of additional factors such as labor contractions and pharmacological agents.

4. 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 number of defined criteria indicative of a normal cardiograph record 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

5. Comparison of Intended Use and Technological Characteristics with Predicate and Reference Device

The following table compares the subject device to the predicate device with respect to the intended use and technological characteristics:

Device and Predicate Device(s):	Predicate Device (K200975)	Subject Device (K241368)

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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
Configuration	Monitoring Hardware only	Monitoring Hardware and **Dawes Redman CTG Software**
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	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

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	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 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	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 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
Ultrasound	Channels: 2	Channels: 2

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	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	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 FHR Range: 30-240 bpm	Channels: 1 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

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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	N/A	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	RS232-CRS: Yes Ethernet – CRS: Yes DVI: 1 channel, DVI-I connector

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	Wireless Telemetry: Yes USB: 2 channels	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 - 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 a new feature, the Dawes Redman CTG Analysis. The Dawes Redman CTG Analysis was cleared as a software algorithm in the reference device (K992607). This difference in technological features does not raise different questions of safety and effectiveness and can be addressed through performance testing.

6. Performance Data

Testing Conducted	Discussion
Software Performance Testing	Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content for the Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "major" level of concern.

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Cybersecurity Testing	Cybersecurity risk management and testing were conducted following FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". Documentation was provided to demonstrate compliance with cybersecurity best practices, including threat modeling, risk assessment, and mitigation strategies. The device underwent verification and validation testing to ensure protection against unauthorized access, data breaches, and potential cyber threats.

7. Conclusion

The non-clinical testing discussed above demonstrates that the Sonicaid Team3 is as safe and effective as the predicate device and supports a determination of substantial equivalence.