June 24, 2020

Huntleigh Healthcare Limited
Steve Monks
QRE Director
35 Portmanmoor Road
Cardiff, CF24 5HN
UK

Re: K200975
Trade/Device Name: Sonicaid Team3 Antepartum, Sonicaid Team3 Intrapartum
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal Monitoring System and Accessories
Regulatory Class: II
Product Code: HGM, HEL, HGP, HFM, KXO, DRT, DQA, DXN
Dated: April 9, 2020
Received: April 13, 2020

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 (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,

Monica D. Garcia, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200975

Device Name
Sonicaid Team3 Antepartum, Sonicaid Team3 Intrapartum

Indications for Use *(Describe)*

The Sonicaid Team3 Antepartum and Sonicaid Team3 Intrapartum fetal monitors (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:

1) Single or twin fetal heart rates by means of ultrasound
2) Uterine activity - externally sensed
3) Fetal movement - maternally sensed and externally via ultrasound
4) Maternal heart rate and oxygen saturation via pulse oximetry
5) Maternal non-invasive blood pressure

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

1) Single or twin fetal heart rates by means of ultrasound and/or FECG
2) Maternal heart rate via ECG electrodes
3) Uterine activity - externally or internally sensed
4) Fetal movement - maternally sensed and externally via ultrasound
5) Maternal heart rate and oxygen saturation via pulse oximetry
6) 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.

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510(k) Summary
K200975

Date Summary Prepared:	June 18, 2020
Submitter/Applicant:	Huntleigh Healthcare Limited Unit 35, Portmanmoor Road Cardiff CF24 5HN United Kingdom
Telephone:	+44 (0)2920 485885
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Contact:	Steve Monks – QRE Compliance Director

5.1 Device Information

Device Trade Name:	Sonicaid Team3 Antepartum, Sonicaid Team3 Intrapartum
Regulation Name:	Perinatal monitoring system and accessories
Regulation Number:	21 CRF 884.2740
Product Codes:	HGM, HEL, HGP, HFM, KXO, DRT, DQA, DXN
Product Code Name:	HGM, system, monitoring, perinatal 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
Regulatory Class:	II
Review Panel:	Obstetrics/Gynecology

5.2 Predicate Device Information

Predicate Device:	Sonicaid FM820E and FM830E (K090285) manufactured by Huntleigh Healthcare Ltd., Diagnostic Products Division. The predicate device has not been subject to a design-related recall.

5.3 Indications for Use

The Sonicaid Team3 Antepartum and Sonicaid Team3 Intrapartum fetal monitors (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:

1) Single or twin fetal heart rates by means of ultrasound
2) Uterine activity – externally sensed
3) Fetal movement – maternally sensed and externally via ultrasound
4) Maternal heart rate and oxygen saturation via pulse oximetry
5) Maternal non-invasive blood pressure

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

1) Single or twin fetal heart rates by means of ultrasound and/or FECG
2) Maternal heart rate via ECG electrodes
3) Uterine activity – externally or internally sensed
4) Fetal movement – maternally sensed and externally via ultrasound
5) Maternal heart rate and oxygen saturation via pulse oximetry
6) Maternal non-invasive blood pressure

5.4 Device Description

The Sonicaid Team3 is a mains / battery powered multi-function fetal monitor designed for use in clinical and hospital environments during antepartum and intrapartum phases of pregnancy.

The Sonicaid Team3 is designed for use at the bedside; there is a wall mounting bracket available as well as a trolley for fixed or transportable use. The unit may also be used free-standing on a work surface.

The units are powered either from local mains electrical supply or an optional internal rechargeable battery.

The Sonicaid Team3 fetal monitors include the following:

- 8.4” Color LCD Display with LED backlighting.
- Touch screen user interface.
- Monitoring of up to two fetal heart rates via independent ultrasound transducers.
- Monitoring of maternal uterine activity via external tocodynamometer (Toco) or internal intra-uterine pressure (IUP) transducers.
- Monitoring of maternal oxygen saturation (SpO_2) and heart rate via pulse oximetry sensor.
- Monitoring of maternal Non-Invasive Blood Pressure (NIBP).

- Monitoring of fetal heart rate via ECG.
- Maternal heart rate (eMHR).
- Capture of maternally sensed fetal movements via a cabled switch.
- Chart printout via (optional) inbuilt thermal printer
- Data output via RS232.

Model Names: Sonicaid Team3 Antepartum: TEAM3A
Sonicaid Team3 Intrapartum: TEAM3I

5.5 Comparison of Intended Use and Technological Characteristics

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

Device & Predicate Device(s):	Subject Device K200975	Predicate Device K090285
General Device Characteristics		
Manufacturer and Device	Huntleigh Healthcare Ltd. Sonicaid Team3 Antepartum and Sonicaid Team3 Intrapartum	Huntleigh Healthcare Ltd. Sonicaid FM830 Encore
Classification	II	II
Product Code	HGM	HGM
Regulation	21 CFR 884.2740	21 CFR 884.2740
Indications for Use	The Sonicaid Team3 Antepartum and Sonicaid Team3 Intrapartum fetal monitors (Team3 fetal monitors) 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: 1) Single or twin fetal heart rates by means of ultrasound 2) Uterine activity - externally sensed 3) Fetal movement - maternally sensed and externally via ultrasound 4) Maternal heart rate and oxygen saturation via pulse oximetry 5) Maternal non-invasive blood pressure	The Huntleigh Healthcare Ltd Sonicaid FM820 and FM830 Encore fetal monitors are indicated for use by trained healhtcare professionals in non-invasive and invasive monitoring of physiological parameters in pregnant adult human females, and fetuses, during the intrapartum and antepartum periods of pregnancy. The devices are intended for use in clinical and hospital-type facilities. They are not intended for use in intensive care units, operating room, or in transport monitoring applications. Sonicaid FM820E is suitable for use when there is a need to monitor the following physiological parameters: • single or twin fetal heart rates by means of ultrasound • fetal or maternal heart rate by ecg • uterine activity-externally or internally sensed • fetal movement-

	Sonicaid Team3 Intrapartum is suitable for use when there is a need to monitor the following physiological applications: 1) Single or twin fetal heart rates by means of ultrasound and/or FECG 2) Maternal heart rate via ECG electrodes 3) Uterine activity - externally or internally sensed 4) Fetal movement - maternally sensed and externally via ultrasound 5) Maternal heart rate and oxygen saturation via pulse oximetry 6) Maternal non-invasive blood pressure	maternally sensed Sonicaid FM830E is suitable for use when there is a need to monitor the following physiological parameters: • single or twin fetal heart rates by means of ultrasound • fetal or maternal heart rate by ecg • uterine activity-externally or internally sensed • fetal movement-maternally sensed • maternal heart rate and oxygen saturation via pulse oximetry • maternal non-invasive blood pressure
Electrical Safety – Device Classification		
Protection against ingress of water and particulates	Main unit: IP30 Main unit with protective cover: IP31 Transducers: IPX7 (Ultrasound, TOCO)	Main unit: Not provided Main unit with protective cover: Not provided Transducers: IPX4 (TOCO), IPX7 (Ultrasound)
Ultrasound		
Channels	2	2
FHR Range	30 – 240 bpm	30 – 240 bpm
Mode	Directional Pulsed Laser	Directional Pulsed Laser
Repetition Rate	3 kHz	3 kHz
Frequency	1 MHz	1 MHz
Resolution	16 bits	16 bits
Alerts	High and low heart rate Signal Loss	High and low heart rate Signal Loss
Safety	Type CF	Type CF
Connector	3 x Huntleigh 12-pole socket	2 x Nikolay 12-pole socket
Ultrasound Transducer	Sonicaid ACC-OBS-008	Sonicaid ACC-OBS-008
TOCO		
TOCO Range	0 – 100 relative units	0 – 100 relative units
Channels	1	1
TOCO Resolution	100% = 120 g	100% = 120 g
Offset range	+ 375 g	+ 100 g
Alerts	TOCO persistence alert (TPA)	None
Safety	Type CF	Type CF
Connector	Huntleigh 12-pole (pink)	Nikolay 12-pole (pink)
Intrauterine Pressure Sensor		
Channels	1	1
Sensor	Intran Plus IUP 400 (K955443)	Intran Plus IUP 400 (K955443)
Safety	Type CF	Type CF
Connector	Huntleigh 12-pole (pink)	Nikolay 12-pole (pink)
Fetal ECG		
Technique	Peak-peak detection technique	Peak-peak detection technique
HR range	30 bpm – 240 bpm	30 bpm – 240 bpm

HR resolution	± 1 bpm over the range 100–180 bpm ± 2 bpm outside range	± 1 bpm over the range 100–180 bpm ± 2 bpm outside range
Input impedance	10M Ohm	10M Ohm
Input signal range	30 – 500 µV peak-to-peak	30 – 500 µV peak-to-peak
DC Offset	± 2 V CM ± 300 mV Differential	± 2 V CM ± 300 mV Differential
Noise	<10 µV peak-to-peak	<10 µV peak-to-peak
Defibrillator protection	Yes	Yes
Alerts	High & low heart rate Loss of contact*	High & low heart rate Loss of contact
Connector	Huntleigh 12-pole (green)	Nikolay 12-pole (white)
Safety	Type CF	Type CF
Fetal ECG Cables	Cable Safelinc (ACC-OBS-066) Cable Qwikconnect (ACC-OBS-068)	Cable Safelinc (ACC-OBS-022) Cable Qwikconnect (ACC-OBS-023) Cable Philips (ACC-OBS-007)
Sp02		
Saturation range	0% - 99%	0 – 100%
Saturation accuracy	0-69%: Unspecified 70-100%: ±2 digits displayed	0% ~ 69%: Unspecified 70-99%: ± 2 digits displayed
PR measurement range	30 – 240 bpm	20 – 250 bpm
Pulse Rate Accuracy	±3 bpm	±1 bpm
Connector	Huntleigh Mini 12-pole	Idu 12-pole
NIBP		
Blood pressure range	Systolic pressure: 25mmHg ~ 280mmHg Diastolic pressure: 10mmHg ~ 220mmHg	Systolic pressure: 50mmHg ~ 255mmHg Diastolic pressure: 10mmHg ~ 220mmHg
Measuring accuracy	± 1.7 mmHg	± 3 mmHg or ±2%, whichever is greater
Cuff pressure protection	300 mmHg 15 sec duration	310 mmHg 160 sec max measurement time
PR measurement range	30 – 240 bpm	40 – 200 bpm
PR measurement accuracy	Validated according to ISO 81060-2	Meets requirements of ANSI/AAMI SP10: 1992 and 2012
Alerts	Systolic high/low Diastolic high/low Cuff too loose Cuff air leak Movement artefact excessive Over-pressure Measurement time exceeded	Air leak Movement, Overpressure
Safety	Type CF	Type CF
Maternal ECG / eMHR		
Channel	1	1
Reference	eMHR	MECG
MHR Range	30 – 240 bpm	30 – 240 bpm
Input Range	500 µV – 5 mV peak-to-peak	Not provided

Alerts	High & low heart rate Loss of contact	Disconnection Signal loss Heart rate goes above or below preset limits.
Safety	Type CF	Type CF
Connector	Huntleigh Mini 7-pole	Nikolay 12-pole (white)
Patient Event Marker		
Safety	Type B	Type B
Connector	6.35 mm Jack 3-pole	6.35 mm Jack 3-pole
Part Number	7775-6901	7775-6901
Printer – unchanged from predicate		
Paper width	128mm thick film thermal array	128mm thick film thermal array
FHR scaling	30–240 bpm or 50–210 bpm*	30–240 bpm or 50–210 bpm*
Speeds	Standard: 1 cm/min, 2 cm/min, 3 cm/min 20 cm/min fast forward	Standard: 1 cm/min, 2 cm/min, 3 cm/min 10 cm/min rapid print
Resolution	8 dots/mm	8 dots/mm
Paper out buffer	100 hours	Not provided
Paper	Plain thermal paper, z-fold, 45 m length	Plain thermal paper, z-fold, 45 m length
Physical Device Characteristics		
Screen	LCD	LCD
Screen dimensions	17 x 12.8cm (6.7 x 5”)	11.5 cm x 8.6 cm (4.5 x 3.4 ”)
Resolution	800 x 600 (SVGA)	320 x 240
Power supply	AC or battery	AC
Operating voltage	AC 85 – 246 V*	AC 90 – 240 V
Line frequency	50/60 Hz	50/60 Hz
Battery	Rechargeable Lithium-ion Battery	None
Dimensions	32x23x23.4 cm	35.8 x 36.3 x 39.2 cm
Weight	6 kg	16 kg
Operating temperature	10 ºC ~ 40 ºC	10 ºC ~ 35 ºC
Transport/storage temperature	-20 ºC ~ 50 ºC	-20 ºC ~ 50 ºC
Operating humidity	15% ~ 90% (relative humidity)	10% ~ 75% (relative humidity)
Transport/Storage humidity	10% ~ 90% (relative humidity)	10% ~ 90% (relative humidity)
Operating atmospheric pressure	70 kPa ~ 106 kPa	68 kPa ~ 106 kPa
Transport/storage atmospheric pressure	70 kPa ~ 106 kPa	68 kPa ~ 106 kPa

The Sonicaid Team3 Antepartum and Sonicaid Team3 Intrapartum have the same intended use as the predicate device – to monitor the progress of labor and fetal status. As noted in the table above, the Sonicaid Team3 fetal monitors have different technological characteristics compared to the predicate device. However, these different technological characteristics do not raise different questions of safety and effectiveness.

5.6 Summary of Non-Clinical Tests

The following performance data were provided in support of the substantial equivalence determination:

Testing Conducted	Discussion
Biocompatibility Testing -Cytotoxicity -Sensitization -Irritation	The biocompatibility evaluation of the device was conducted in accordance with *ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.* The subject device and accessories are considered a skin contacting device (intact) for a duration of <30 days.
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.
Electronic Hardware Performance Testing	Testing provided verification of the Sonicaid Team3 main Printed Circuit Board (PCB) performance including Automatic Test Equipment (ATE) testing, functional testing Unit Under Test (UUT), cooling fan speed controller, battery charging indication, switch ON feedback and MASIMO/NELLCOR interface.
Mechanical Performance Testing	Testing provided verification of mechanical performance including general, physical, environment, product labelling, instructions for use, packaging, durability and life testing.
Functional Performance Testing	Testing provided verification of the hardware software interaction. Functions tested include ultrasound, external devices, TOCO, SpO_2, NIBP, alarms, FECG enhancements, eMHR, wireless, system, battery life, battery charge and fetal movement detection.
Electrical Safety Testing	Electrical safety testing was conducted on the product by a third-party laboratory, UL. Testing confirmed the device complies with AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012. Medical Electrical Equipment: Part 1: General Requirements.
EMC Testing	EMC testing was conducted on the product by a third-party laboratory. Testing confirmed the device complies with AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012. Medical Electrical Equipment: Part 1: General

	Requirements.
Environmental Performance Testing	Testing provided verification of the operating and storage temperature, humidity and atmospheric pressure, and non-operational shock and vibration.

5.7 Conclusion

The results of the performance testing described above demonstrate that the Sonicaid Team3 Antepartum and Sonicaid Team3 Intrapartum fetal monitors are as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.