sonicaid FM800 Encore

Fetal Monitor

FDA 510(k) Premarket Notification

Section 5

510(k) Summary

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510(k) Summary

5.1 APPLICANT INFORMATION

Submitter:	Huntleigh Healthcare Limited Diagnostic Products Division
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Prepared:	26 January 2009

5.2 DEVICE INFORMATION

Proprietary Name:	Sonicaid FM820E and FM830E (E=Encore)
Common/Classification Name:	Perinatal Monitoring Device & Accessories

5.3 IDENTIFICATION OF LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS CLAIMED

Predicate Device 1:	Sonicaid FM830 (k002150)
Predicate Device 2:	RDT Limited Tempus IC™ Patient Monitor (k082718)

5.4 NEW DEVICE DESCRIPTION

5.4.1 Outline

The FM820E and FM830E are fetal/maternal monitors designed for use in clinical and hospital environments during the ante-partum and intra-partum phases of pregnancy.

Both units are designed for use at the bedside and the range includes a wall mounting bracket and a trolley for fixed or transportable use. The units may also be used free-standing on a work surface.

The FM820E and FM830E are powered from the local mains electrical supply.

The FM820E includes the following facilities:

- Monitoring of one or two fetal heart rates via two independent ultrasound transducers.
- Monitoring of maternal uterine activity either via external (Toco) or internal (IUP) transducers.
- Monitoring of maternal or fetal heart rate via ECG.
- Capture of maternally sensed fetal movements via cabled switch.
- Display of vital signs parameters via colour LCD screen.
- Control interface via combination of dedicated and "soft" function buttons in conjunction with on-screen prompts.
- Chart printout via inbuilt thermal printer.
- Connection to Central Monitoring System possible via RS232 or Ethernet.

- Audio and visual alerts (user set limits).

The following facilities are provided on the FM830E model in addition to the above:

- Monitoring of maternal oxygen saturation and heart rate via pulse oximetry sensor.
- Monitoring of maternal Non-Invasive Blood Pressure (NIBP) via inflatable cuff.

The connections for the additional facilities are incorporated in a "side pod", which extends the area of the front panel. Field upgrade of the FM820E to FM830E specification is not allowed.

5.4.2 Technology & Operating Principles

5.4.2.1 Ultrasound

The ultrasound channels use identical transducers, each incorporating 8 ceramic piezo elements electrically connected in parallel. The operating principle is as follows:

The monitor drives the transducer with an excitation signal, comprising a "burst" of ac electrical current at the nominal operating frequency of the transducer. The piezo elements have a characteristic response of a tuned circuit, leading to highest efficiency at a particular nominal frequency – in this case 1MHz.

The choice of frequency, the geometry and size of the individual elements, and their arrangement within the transducer affects the achievable degree of penetration, beam width and discrimination.

After each burst, the monitor "listens" for signals picked up by the transducer, which now acts as a pickup device, with peak response at the characteristic frequency. These signals will be acoustic reflections of the original transmitted burst, delayed in time according to the distance travelled within the body of the mother, and the fetus. The Doppler Effect causes reflections from moving body parts to reflect signals with a shift in frequency; it is these frequency-shifted reflections that are detected and processed within the unit to determine fetal heart activity. Audible feedback is provided to enable the operator to direct the "beam" of ultrasound so as to provide optimal pickup of the fetal heart activity, recognisable by a characteristic sound. Once the optimum location has been found, the transducer is held in place by an elasticated belt.

The second ultrasound transducer is similarly used in the case of a twin pregnancy.

The signals obtained from the ultrasound channels are digitally processed to extract the fetal heart rate(s).

The ultrasound channels rely on the transducer insulation for patient isolation from the circuitry of the FM800E, which is referenced to mains earth.

5.4.2.2 Toco/IUP

The tocograph transducer is a pressure sensitive device that is strapped to the mother's stomach with an elasticated belt. The central part of the contact area is in the form of an elastic membrane that is free to move with respect to the main body of the device. Contractions of the uterus cause changes in pressure on the membrane and these are translated to electrical signals by means of strain gauges mounted on an internal steel spring.

The IUP sensor is an alternative method of picking up contractions. A pressure-sensitive probe is inserted into the birth canal and directly monitors changes in uterine pressure. The IUP probe is a pre-sterilised single use device.

The tocograph and IUP sensors use similar principles (strain gauge bridges). Being two alternatives for measuring the same parameter, they are mutually exclusive. The two devices use the same input connector and signal processing circuitry. The type of transducer in use (Toco or IUP) is identified by electrical coding of the connections.

The signals derived from the tocograph and IUP sensor are digitised and processed for printout and display.

The Toco/IUP channel is electrically isolated from the main circuitry of the FM800E by transformer and optical isolators.

5.4.2.3 ECG

The FM800E has one ECG channel, which can be used for monitoring either maternal or fetal heart rates.

Maternal ECG signals are derived from two contact pads placed on the mother's torso. A "reference" connection is also made – either via a third pad, or an electrode strapped to the leg.

Fetal ECG signals are derived from a scalp clip, which provides the two signal connections. The reference connection is made via an electrode strapped to the mother's leg.

The FM800E uses an "active reference drive", whereby the reference electrode is incorporated within a negative feedback loop and driven with the inverse of the common-mode signal derived from the two signal electrodes. This acts to reduce common-mode signal and improves signal to noise ratio. The ECG channel also has an "active screen (shield) drive", which ensures that the cable screen (shield) is maintained close to the common-mode potential, further negating interference effects. This drive signal is not a patient contact signal.

The ECG channel signal is digitised and processed for printout and display.

Maternal heart rate information is naturally useful for monitoring the well-being of the mother. However, the FM800E also cross-checks the maternal HR with the fetal HR derived from the ultrasound channel(s) and provides a warning if there is similarity. This helps prevent false monitoring of maternally derived HR signals, which is a major risk in fetal monitoring.

Fetal ECG provides a more reliable signal during the intrapartum stage.

The ECG channel is electrically isolated from the main circuitry of the FM800E by transformer and optical isolators. The type of transducer in use (Maternal or Fetal) is identified by electrical coding of the connections so that from the user perspective, selection is "automatic".

5.4.2.4 Fetal Event Marker

A simple push button switch is provided to capture fetal movements sensed by the mother. Pressing the switch causes a message to be briefly displayed on the screen, and a marker to be printed on the tocograph trace.

The Fetal Event Marker input relies on the switch insulation for patient isolation from the circuitry of the FM800E, which is referenced to mains earth.

5.4.2.5 Maternal SpO2

This facility is incorporated in the FM830E version only (i.e. not the FM820E). It uses a third party module, which provides a data signal to the FM830E's processing system.

In use, a sensor, in the form of a spring-loaded clip, is placed on the mother's finger. The sensor emits two wavelengths of light, one red and one infrared, through body tissue to a photodetector. The principle of operation is on the basis that oxygen-rich blood absorbs less red light than oxygen depleted blood. The maternal oxygen saturation and heart rate are derived and passed to the FM830E's processing system in the form of a serial data stream. This information is displayed on the screen and printed on the chart.

Apart from being used to monitor the well-being of the mother, as with MECG, the FM830E also cross-checks the SpO2 derived MHR with the fetal HR derived from the ultrasound and/or FECG channel(s) and provides a warning in the event of coincidence.

Interface with the patient is in the form of low energy light transmission only, which provides total electrical isolation. In addition, this section is isolated from the main electronics by transformer and optical isolators.

5.4.2.6 Maternal Non-Invasive Blood Pressure

This facility is incorporated in the FM830E version only (i.e. not the FM820E). It uses a third party module, which provides a serial stream to the FM830E's processing system.

In use, an inflatable cuff is placed around the mother's arm. A measurement cycle begins with the cuff being inflated; the system senses both the cuff pressure, and the oscillometric signal generated by arterial pulses. From these, the systolic and diastolic blood pressures are determined, along with the MHR. The cycle ends with the cuff being deflated. Measurements can be made manually, on an as-required basis, or the FM830E can be set to take measurements periodically.

The NIBP module incorporates fail-safe mechanisms to prevent over-inflation of the cuff, including a separate safety microprocessor, which separately monitors cuff pressure and can shutdown the pump and open the valves in the event of a fault.

The NIBP information is displayed on the screen and printed on the chart. The MHR information is only valid at the time of the measurement and is displayed for a limited time - but only if no continuous method of obtaining MHR (ECG or SpO2) is available.

Interface with the patient is via an air tube only, which provides total electrical isolation.

5.4.2.7 Display

The FM800E uses a colour TFT Liquid Crystal Display with a resolution of 320x240 dots (1/4 VGA). This is used to display the following information:

- Fetal heart rate (FHR) from ultrasound channels 1 and/or 2.
- Uterine contractions from the Toco/IUP channel.
- Fetal or Maternal heart rate (FHR or MHR) from fetal or maternal ECG.
- Maternally sensed Fetal Events in the form of an on-screen message.
- MECG or FECG waveform trace or "baby" graphic.
- CTG Trace. The unit stores in excess of 24 hours of trace data and this can be recalled and displayed on screen.
- Maternal oxygen saturation and heart rate (FM830E only).
- Maternal blood pressure and heart rate (FM830E only).

In general, information is colour matched to the connectors used for the different channels – e.g. green for ultrasound, pink for toco/IUP, white for ECG.

The display is also used for configuration in conjunction with the front panel "soft" buttons. Parameters that can be changed include:

- Alert (alarm) thresholds.
- Time and date.
- Patient details.
- Printer settings (speed, headings)
- International settings (language, date format etc.).
- "Baby" graphic and FECG/MECG waveform display.
- "Easinote" defaults (pre-entered chart annotation text).
- Interface settings.

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5.4.2.8 Printer

The FM800E incorporates a chart recorder that provides a hard copy printout on continuous "fan fold" thermal paper. Long life (25 year) archival paper is available.

Print speed can be set to 1, 2 or 3 cm/s.

The monitor incorporates a number of dedicated front panel buttons and indicators for printer control as follows:

- Printer on/off (with indicator)
- Paper Advance
- "Easinotes" annotation

The chart content varies according to the model (FM820E or FM830E), and which transducers and sensors are connected, but can include:

- Patient and hospital information (header)
- Date and time
- Fetal heart rate (FHR) from ultrasound channels 1 and/or 2.
- Uterine contractions from the Toco/IUP channel.
- Fetal or Maternal heart rate (FHR or MHR) from fetal or maternal ECG.
- Maternally sensed Fetal Events in the form of printed markers.
- "Easinote" annotation text.
- Cross-channel heart rate coincidence warnings.
- Maternal oxygen saturation and heart rate (FM830E only).
- Maternal blood pressure and heart rate (FM830E only).

Impending paper exhaustion is signalled by a coloured band pre-printed on the paper. A sensor detects when the paper is exhausted, or the printer tray is removed; up to ten minutes of trace data are stored in memory, giving adequate time to change the paper pack. The buffered data are then printed, ensuring that there are no gaps in the printout.

5.4.2.9 Interfaces

The FM800E incorporates the following interfaces on the rear panel:

- RS232 connection to Central Monitoring System.
- RS232 connection to external device (future provision).
- Ethernet connection to Central Monitoring System.

The RS232 and Ethernet links are electrically isolated from the main FM800E circuitry.

5.4.2.10 User Alerts

The monitor has the facility to provide audio/visual alerts to draw the operator's attention to any of the following occurrences:

- Ultrasound: Signal loss. Heart rate goes above or below preset limits.
- ECG: Disconnection. Signal loss. Heart rate goes above or below preset limits.
- MSpO2: Signal loss. Maternal oxygen saturation falls below a preset limit.
- NIBP: Systolic or diastolic blood pressure go outside preset limits.
- Maternal & Fetal heart rate coincidence.

All limits are determined by the user and are not therefore in themselves indicative of potential harm or the need for clinical intervention.

5.4.2.11 Audio Output

The FM800E incorporates a built-in loudspeaker. This is used for audible feedback of:

- Ultrasound.
- MECG/FECG.
- Sp02.

Each has a characteristic sound, recognisable by clinicians, and helps in optimising the position of sensors and transducers in order to give the best signal.

The loudspeaker is also used to provide user feedback in the form of "beeps" to warn of alarm conditions etc.

There are three dedicated buttons on the front panel associated with the loudspeaker:

- Channel select (US, ECG or Sp02). The selected channel is apparent from the display.
- Volume Increase
- Volume Decrease

5.5 STATEMENT OF INTENDED USE

Huntleigh Healthcare Ltd Sonicaid FM800 Encore series fetal monitors are indicated for use in non-invasive and invasive monitoring of fetal and maternal vital signs during the intrapartum and ante-partum periods.

Sonicaid FM820E provides comprehensive fetal monitoring facilities, offering twin ultrasound fetal heart rate, fetal or maternal ECG channel, external and internal uterine activity monitoring and maternally sensed fetal movements.

Sonicaid FM830E additionally provides maternal monitoring with the facility for simultaneous monitoring of maternal pulse oximetry and non-invasive blood pressure.

The device is intended for use by healthcare professionals for monitoring fetal and adult patients in clinical and hospital-type facilities. It is not intended for use in intensive care units, operating rooms or in transport monitoring applications.

The FM820/830 Encore is not intended for use with patients fitted with cardiac pacemakers, during defibrillation, while undergoing surgery, or while MRI scanning is taking place.

5.6 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICES

Note that further predicate device comparison information can be found in section 12 of this submission.

5.6.1 Comparison with Sonicaid FM830 (k002150)

This summary compares the Sonicaid FM830E to the legally marketed predicate device, the Sonicaid FM830 (k002150). The FM820E contains a subset of the functions of the FM830E (and is similar to the FM820).

CHARACTERISTIC		Predicate Device Sonicaid FM830 (k002150)	Submitted Device Sonicaid FM830 Encore	RATIONALE
Human Interface				
Display		Monochrome Electro-luminescent 320x240	Colour LCD 320x240	Colour display => clearer user interface. Reduced power consumption.
Controls		Membrane type push buttons with dedicated and "soft" keys.	Membrane type push buttons with dedicated and "soft" keys.	Same.
Printer		128mm Thick Film Thermal Array, 8 dots/mm.	128mm Thick Film Thermal Array, 8 dots/mm.	Same.
Connectors:				
Front	Ultrasound 1&2	U'sound 1& 2: Nikolay 12-pole, Yellow & Blue	U'sound 1& 2: Nikolay 12-pole, Green x2	New ultrasound transducers not compatible with FM800
	Toco/IUP	Nikolay 12-pole, Pink	Nikolay 12-pole, Pink	Same. Transducers are compatible
	FECG	Nikolay 12-pole, Blue (shared with US2).	Nikolay 12-pole, White (shared with MECG)	FECG no longer shared with US2. Electrode system is compatible.
	MECG	Nikolay 12-pole, Blue	Nikolay 12-pole, White (shared with FECG)	Connectors keyed differently. MECG electrode system is compatible.
	MSpO2	Odu 12-Pole, Metal	Odu 12-Pole, Plastic	Plastic connector improves patient isolation.
	NIBP	Pneumatic	Pneumatic	Same.
Rear	RS232 (CRS)	9-Way "D-type" (F) x1	9-Way "D-type" (F) x1	Same.
	RS232 (Unallocated)	9-Way "D-type" (F) x2	9-Way "D-type" (F) x1	Same type, quantity reduced due to redundancy.
	RS485 (Axis)	6-Pole PCC x1	-	Axis system now obsolete.
	VGA (Ext. Monitor)	15-Way HD "D-type" (F) x1	-	External monitor not supported – clinically redundant.
	Ethernet	-	RJ45 x1	Improves CRS connection options.
Side	Event Marker	6.35mm Jack x2	6.35mm Jack x2	Same
Power Requirements				
Voltage		Auto-switches in two ranges: 100-120 & 200-240.	90-240Vac.	Increased supply flexibility.
Consumption		100VA max.	100VA max.	Same.
Ultrasound				
Transducers - Physical		74x27mm (Dia x Height) 7-element piezo	79x27mm (Dia x Height) 8-element piezo	Similar.
Transducers - Frequency		1.5MHz (US1) and 2MHz (US2)	1MHz (both channels)	Improved pickup & discrimination in conjunction with new software. Product rationalisation.

CHARACTERISTIC	Predicate Device Sonicaid FM830 (k002150)	Submitted Device Sonicaid FM830 Encore	RATIONALE
Signal Processing	Analogue/Digital	Analogue/Digital	Similar (new DSP algorithms introduced for improved detection over a wider range of conditions).
Measured Acoustic Output (I_{spta}) FDA Track 1	1.5MHz: 11mW cm^{-2} 2.0MHz: 7.3mW cm^{-2}	2.1mW cm^{-2}	Superior signal processing has enabled a reduction in acoustic power output.
Audio Feedback	Analogue	Digital	At 1MHz, raw analogue Doppler frequency is too low for good audibility. Improved artefact rejection.
Safety	Insulated transducer	Insulated transducer	Same
Tocograph			
Transducers - Physical	Floating piston type with adhesive membrane.	New moulding, similar to u/s with overmoulded elastomer faceplate.	Lower maintenance. Improved patient comfort. Easier to clean, reduced chance of infection.
Transducers - Functional	Double strain gauge/spring assembly.	Double strain gauge/spring assembly.	Same.
Signal Processing	Analogue/digital.	Analogue/digital. Improved processing algorithms.	Product improvement
Safety	Insulated transducer + isolation Barrier.	Insulated transducer + isolation Barrier.	Same.
IUP			
Compatible Probes	Intran Plus IUP 400 (k955443)	Intran Plus IUP 400 (k955443)	Same.
Safety	Insulated transducer + isolation Barrier.	Insulated transducer + isolation Barrier.	Same.
MECG/FECG			
Compatible Electrodes - MECG	Not known	Skintact F-TB (k040249)	Comparison not possible.
Compatible Electrodes – FECG	Graphic Controls (k905830)	Safelinc Fetal Spiral Electrode (k904745) GE Quik-Connect Spiral Electrode (k911657)	Options are legally marketed and are validated for use with the submitted device.
Signal Processing	Analogue/digital.	Analogue/digital (enhanced)	Performance improvement under sub-optimal conditions.
Safety	CF level protection.	CF level protection.	Same (BF is minimum requirement).
NIBP			
OEM Technology	Suntech Alta	Suntech Advantage	Alta modules no longer produced. Superseded by Advantage.
Compatible Cuffs	Not known	Suntech APC series (k051904)	Comparison not possible.
Maternal Temp			
Function	Included on FM830	Not included	Not clinically beneficial.
Accessories			
Wall Bracket	Not known	Huntleigh Healthcare ACC223	Comparison not possible.
Trolley	Not known	Huntleigh Healthcare ACC-OBS-003	Comparison not possible.

CHARACTERISTIC	Predicate Device Sonicaid FM830 (k002150)	Submitted Device Sonicaid FM830 Encore	RATIONALE
Software			
CTG Trace	Not implemented	Trace data stored in memory for review on screen – up to 72 hours.	Product improvement.

5.6.1 Comparison with RDT Tempus IC™ Patient Monitor (k082718)

The OEM technology for the Maternal SpO2 function differs in the Sonicaid FM830E from the Sonicaid FM830 (k002150). In respect of this function, the submitter claims Substantial Equivalence to another predicate device – the Tempus IC™ Patient Monitor (k082718) manufactured by Remote Diagnostic Technologies Limited of The Old Coach House, The Avenue, Farleigh Wallop, Hampshire, RG25 2HT, United Kingdom.

CHARACTERISTIC	Predicate Device Tempus IC™ (k082718)	Submitted Device Sonicaid FM830 Encore	RATIONALE
MSpO2			
OEM Technology	BCI (Smiths Medical) WW3711 "B2"	BCI (Smiths Medical) WW3711 "B2"	Same.
Compatible Sensors	Proprietary.	BCI Adult Comfort Clip 3444 (k974697) Nellcor Durasensor DS-100A (k863784)	Use of BCI 3444 and Nellcor DS-100A is supported by BCI clinical trials (see section 12 for further details).

5.7 TESTS CARRIED OUT IN SUPPORT OF A DETERMINATION OF SUBSTANTIAL EQUIVALENCE

5.7.1 Non-Clinical Tests

Electrical safety is to be confirmed by testing to the requirements of IEC 60601-1: 1988 and EN 60601-1-1: 2000.

Electromagnetic compatibility (EMC) is to be confirmed by testing to the requirements of IEC 60601-1-2: 2007.

Substantial equivalence to the FM800 predicate device (k002150) is confirmed by comparative bench testing. See document 7515101 – *FM800E Comparative Bench Test Summary*, which can be found in section 18 of this submission.

No specific tests have been carried out by Huntleigh Healthcare to support substantial equivalence to the Tempus IC™ Patient Monitor (k082718). However, this uses the same OEM module (BCI WW3711) as used in the FM830E, and the aim of the bench tests carried out in this regard has been to verify that the raw data output from the OEM module is correctly displayed and printed on the FM830. See document 7514502 – *FM800E MsPO2 Verification Protocol & Results*, which can be found in section 18 of this submission.

5.7.2 Clinical Tests

No specific clinical tests were carried out to determine substantial equivalence. However, this submission references clinical trials carried out by the OEM providers of the SpO2 technology to validate the use of the specified finger sensors.

User evaluation trials are to be carried out to verify the effectiveness of the FM830E in clinical situations. This submission includes a copy of the proposed User Evaluation Trial protocol.

See section 20 of this submission for further details.

5.8 CONCLUSIONS

5.8.1 Safety

The Electrical Safety and EMC tests to be carried out on the Sonicaid FM830E will confirm that it is at least as safe as the Sonicaid FM830 (k002150) predicate device.

5.8.2 Effectiveness

The FM830E has been designed to provide improved performance, clearer presentation of information and easier use compared with the FM830 predicate device (k002150). This is to be confirmed by User Evaluation trials in clinical situations in the home market.

5.8.3 Performance

Comparative bench tests confirm that the performance of the Sonicaid FM830E is at least as good as the Sonicaid FM830 (k002150) predicate device.

The overall conclusion is that the FM820/830E is as safe, as effective, and performs as well as, or better than, the FM820/830 (k002150) predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2009

Mr. Graham Booth
Technical Manager – Obstetric Products
Huntleigh Healthcare Limited
Diagnostic Products Division
35 Portmanmoor Road
Cardiff, CF24 5HN
UNITED KINGDOM

Re: K090285
Trade/Device Name: Sonicaid FM820 & FM830 Encore Series Fetal Monitors
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: June 9, 2009
Received: June 11, 2009

Dear Mr. Booth:

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. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number: K090285

Device Name: Sonicaid FM820/830 Encore

Indications for Use:

The Huntleigh Healthcare Ltd Sonicaid FM820 and FM830 Encore fetal monitors are indicated for use by trained healthcare 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 rooms 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 via ECG
- Uterine activity – externally or internally sensed
- Fetal movement – 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 via 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

Prescription Use
YES
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
NO
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090285