K132650

FEB - 7 2014

HUNTLEIGH

DIAGNOSTIC PRODUCTS DIVISION

Section 5: 510(k) Summary as required by Section 807.92(c)

5.1 APPLICANT INFORMATION

510(k) Submitter	Huntleigh Healthcare Limited, Diagnostic Products Division 35 Portmanmoor Road CARDIFF, CF24 5HN United Kingdom
Contact Name	Laura Garcia Deacon
Contact Title	Regulatory Affairs Engineer
Contact Phone Number	+44 2920 447703
Contact Fax Number	+(44) 2920 492520
Contact Email address	Laura.deacon@huntleigh-diagnostics.co.uk
Prepared:	January 9, 2014

5.2 DEVICE INFORMATION

Proprietary Name:	Sonicaid™ Freedom Wireless Fetal Monitoring System
Common/Classification Name:	Perinatal Monitoring Device & Accessories
Classification	Class II
Product Code	HGM
Classification Regulation	884.2740

5.3 PREDICATE DEVICE

Predicate Device:	Avalon CTS Cordless Fetal Transducer System (K023931)
Owned by:	Philips Medical Systems, Nederland B.V. Post bus 10.000, 5680 DA Best, Netherlands
Manufactured by:	Philips Medizin Systeme Boeblingen GmbH, Cardiac and Monitoring Systems, Hewlett-Packard Str.2, 71034 Boeblingen, Germany

5.4 INDICATIONS FOR USE

Sonicaid™ Freedom Wireless Fetal Monitoring System

The Sonicaid™ Freedom Wireless Fetal Monitoring System ('Freedom') is a wireless transducer system for monitoring fetal heart movement and maternal contractions during intrapartum and antepartum periods of pregnancy.

It is an optional accessory for use with Huntleigh Healthcare Limited's Sonicaid™ FM820 and FM830 Encore Fetal Monitors ('FM800E Monitors') as an alternative to their wired transducers. When connected to an FM800E Monitor, the system monitors:

- Uterine activity by using an external, pressure-sensitive TOCO transducer, and
- Fetal Heart Rate (FHR) by pulsed Doppler ultrasound using an external Ultrasound transducer.

Freedom is suitable for use with pregnant women in clinical and hospital facilities. The transducers are water tight allowing pregnant women to be monitored while they are mobile, stationary or in a bath or shower environment.

This system should only be used by, or under the supervision of, a licensed physician or other health practitioner who is trained in the use of FHR monitors.

5.5 DEVICE DESCRIPTION

The Sonicaid™ Freedom is intended to monitor fetal heart movement and uterine activity by using wireless, non-invasive transducers on pregnant women during antepartum and intrapartum phases of pregnancy. This system is an optional accessory that must be connected to, and used with, a Sonicaid™ FM800E Monitor when a woman wishes to be mobile or in a water environment when being monitored or giving birth.

The Freedom has three major components; the Receiver and Ultrasound ('US') and Tocograph ('TOCO') transducers. The wireless transducers are powered by internal batteries that are recharged when docked on the Receiver.

The Sonicaid ™Freedom operates in the WMTS frequency bandwidth. There are 100 selectable channels available for use. If there is interference when installing the system, then the channel may be changed to achieve clear transmission.

Technology Overview

Receiver

The Receiver must be connected to a Sonicaid™ FM800E Monitor to operate the wireless transducers. The front panel has two docking stations for charging the TOCO and US transducers and for storing them and three sets of visual indicators. These indicators, which inform an operator about the status of the transducers when docked or in use, include:

- The charging indicators ensure that transducers are recognised by the receiver, docked properly and recharging until the battery is fully recharged.
- The transmission indicators confirm that the transducers are in range and there is no interference during use.
- The battery indicator provides the operator with the relative level of battery capacity.

These indicators also inform the operator when there is interference, low battery capacity, when a patient is out of transmission range or if there is a fault.

The back of the Receiver contains the connecting points for the receiving antenna, RF-channel selector, interface to the Sonicaid FM800E Monitor and the power supply input.

The Receiver's internal components drive the system through the microcontroller, selectable radio frequency channels, an antenna and a near field communication ('NFC') transmitter.

Transducers

The US and TOCO transducers are both wireless, water tight and may be used when patients are stationary, mobile or in a water environment.

Ultrasound Transducer

The US transducer detects fetal heart movement by pulsed Doppler ultrasound. This is driven by a master clock that produces the pulse streams necessary for the detection of FHR. Other components include the battery power supply and an RF transmitter.

TOCO Transducer

The TOCO transducer is a pressure sensitive device that detects contractions or uterine activity. The key components within the TOCO transducer are the NFC transmitter, pressure sensor and the battery power supply.

5.6 SUBSTANTIAL EQUIVALENCE

The Sonicaid™ Freedom is substantially equivalent to the cleared predicate device, the Avalon CTS Cordless Fetal Transducer System (K023931).

5.7 TECHNOLOGY COMPARISONS

The Sonicaid™ Freedom and the predicate device are equivalent in the following ways:

- Each system has a Receiver unit with docking stations for each transducer. Both systems have a least one Ultrasound transducer and one TOCO transducer.
- Both wireless transducer systems have been designed as accessories for use with compatible fetal monitoring systems with wired transducers.
- Neither unit can be used as a stand-alone system; both must be used only when they are connected to specified fetal monitoring systems.
- Both systems have TOCO and Ultrasound transducers that are wireless, powered by rechargeable lithium batteries and have the same water ingress rating; these features enable patients to be monitored when they are stationary, mobile or in a water environment.
- Communication between the transducers and the Receiver is via a WMTS frequency band.
- Both systems automatically recharge the transducers' batteries when transducers are docked on their respective Receivers.
- Both systems have similar indicators to monitor the battery capacity and the operating status of the transducers.
- The intended use, indications for use, patient population, clinical settings and operating conditions for monitoring fetal heart movement and uterine contractions are the same.
- Both systems use the same or similar methods and technologies for determining FHR and uterine activity; FHR by Doppler ultrasound and UA by pressure detection.

- The Ultrasound transducer elements from both systems have a similar structure and their acoustic output levels are comparable and within safety limits.

5.8 BENCH TESTS

Verification and validation tests were conducted to demonstrate performance, safety and substantial equivalence to the predicate device. Compliance to the following was achieved:

- Ultrasound Transducer Acoustic Output (IEC 60601-2-37)
- Environmental Requirements (ISO 60068-2)
- Electrical Safety (EN 60601-1)
- EMC (EN 60601-1-2 /FCC)
- Software (EN 62304)
- Material Biocompatibility (ISO 10993)

Simulated bench tests were used to demonstrate that the performance of the Sonicaid™ Freedom Ultrasound and TOCO transducers is comparable to the Sonicaid™ FM800E transducers.

5.9 CLINICAL TESTS

No clinical tests were required to determine substantial equivalence between the Freedom and the predicate device.

5.10 CONCLUSIONS

The conclusions drawn from the data detailed within this submission demonstrate that the Sonicaid™ Freedom is as safe, as effective, and performs as well as the legally marketed Avalon CTS Cordless Fetal Transducer System (K023931).

The Sonicaid™ Freedom does not raise any new concerns regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2014

Huntleigh Healthcare Limited
Laura Garcia Deacon
Regulatory Affairs Engineer
35 Portmanmoor Road
Cardiff, Wales CF24 5HN
United Kingdom

Re: K132650
Trade/Device Name: Sonicaid™ Freedom Wireless Fetal Monitoring System
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: January 9, 2014
Received: January 16, 2014

Dear Laura Garcia Deacon,

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. 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); 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132650

Device Name: Sonicaid™ Freedom Wireless Fetal Monitoring System

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Prescription Use		Over-The-Counter Use
YES	AND/OR	**NO**
(Part 21 CFR 801 Subpart D)		(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)

Herbert P. Lerner -S
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