DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 10, 2015

Airstrip Technologies, Inc.
% Curtis Egan
Sr. Quality, Regulatory & Design Engineer
Certified Compliance Solutions Inc.
11665 Avena Place, Suite 203
San Diego, California 92128

Re: K143114
Trade/Device Name: Sense4baby System Model B+ (MSA)
Regulation Number: 21 CFR 884.2730
Regulation Name: Home Uterine Activity Monitor
Regulatory Class: Class II
Product Code: LQK, MOH, HGM
Dated: December 1, 2014
Received: December 10, 2014

Dear Curtis Egan,

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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 Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143114

Device Name
Sense4Baby System, Model B+ (MSA)

Indications for Use *(Describe)*
The Sense4Baby System Model B+ is indicated for conventional antepartum fetal monitoring applications in pregnancies greater than or equal to 24 weeks gestation. It may be used for antenatal monitoring (e.g., non-stress testing and/or uterine activity monitoring) in a health care setting or home.

It is to be used by health care professionals and patients on the order of a physician.

Before the Sense4Baby System Model B+ is prescribed for home use, the user (patient) must be instructed/trained in proper use of the equipment.

Home uterine activity monitoring has not been shown to prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth.

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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Sense4Baby System B+ 510(k) Submission

1. 510(k) Summary

Submitter:	Airstrip Technologies, Inc.
Address:	565 Pearl St suite 209 La Jolla, CA 92037
Phone number:	(201) 847-4496
Fax number:	(201) 847-4845
Contact person:	Curtis M. Egan
Phone number:	(951) 723-7261
Fax number:	(858) 675-8201

Date prepared:	October 21, 2014
Trade name:	Sense4Baby System, Model B+ (MSA)
Common Name:	Fetal Monitor
Classification Name:	Home Uterine Activity Monitor
Product Code:	LQK, MOH, HGM
Regulation:	21 CFR 884.2730

Substantial equivalence claimed to: Huntliegh Healthcare Limited Fetal Assist, K020390

1.1. Description:

The Sense4Baby System, Model B+ (MSA) is a non-invasive, wireless, external monitoring system used to measure fetal heart rate, maternal heart rate, and uterine contractions during antepartum (non-stress) testing. The system transmits the measured data to a gateway device, and then a HIPAA Compliant web based portal for storage and physician review.

1.2. Indications for Use:

The Sense4Baby System Model B+ is indicated for conventional antepartum fetal monitoring applications in pregnancies greater than or equal to 24 weeks gestation. It may be used for antenatal monitoring (e.g., non-stress testing and/or uterine activity monitoring) in a health care setting or home.

It is to be used by health care professionals and patients on the order of a physician.

Before the Sense4Baby System Model B+ is prescribed for home use, the user (patient) must be instructed/trained in proper use of the equipment.

Home uterine activity monitoring has not been shown to prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth.

1.3. Technological Characteristics

Sense4Baby, Inc. Model B+ (MSA) is substantially equivalent to the predicate device the Huntliegh Healthcare Limited Fetal Assist (K020390).

The Sense4 Baby System Model B+ (MSA) complies with applicable voluntary safety standards, in the areas of:

- Electrical Safety
- Electro-Magnetic Compatibility (EMC)
- Material safety
- Risk Management

Safety testing performed in conformance to these voluntary standards was conducted at accredited independent test facilities to demonstrate that the Sense4Baby System Model B+ (MSA) is as safe and effective as the predicate device. The specific standards employed were:

- IEC 60601-1:2005 + CORR.2 (2007) + A1 (2012), Medical electrical equipment – Part 1: General requirements for safety.
- National deviations of IEC 60601-1: 2005, such as EN 60601-1, Ed. 3 (European Harmonized Standard), AAMI ES 60601-1, Ed. 1 (US National Standard), CSA – C22.2 No 60601-1:2008 (Canadian National Standard).
- IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-2-37:2007 Medical Electrical Equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
- ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009: Biological evaluation of medical devices, Part 5- Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices, Part 10- Tests for irritation and skin sensitization.
- ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems.
- IEC 60529:1989 + A1 (1999) Degrees of protection provided by enclosures (IP Code).

The possibility of hazards arising from hardware and software errors was further minimized in compliance with ISO 14971:2007 and ISO 13485:2003

General Device Characteristics	Sense4Baby System B+ (MSA)	Huntliegh Healthcare Limited Fetal Assist (K020390)
Indication for Use	The Sense4Baby System Model B+ is indicated for conventional antepartum fetal monitoring applications in pregnancies greater than or equal to 24 weeks gestation. It may be used for antenatal monitoring (e.g., non-stress testing and/or uterine activity monitoring) in a health care setting or home. It is to be used by health care professionals and patients on the order of a physician. - Before the Sense4Baby System Model B+ is prescribed for home use, the user (patient) must be instructed/trained in proper use of the equipment. - Home uterine activity monitoring has not been shown to prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth.	The FETAL ASSIST is suitable for use in all conventional antepartum fetal monitoring application from a gestation age of approximately 26 weeks. It is particularly intended for use in the following specific areas: Antenatal monitoring in the hospital, doctors office, health clinic, home or community. External Labor monitoring. Waterbith monitoring using optional waterproof transducers. Home Uterine Activity Monitoring (HUAM) in conjunction with standard high-risk care, for the daily at-home measurement of uterine activity for women with history of preterm birth. Domiciliary Non Stress Testing Applications. NB: before being used in domiciliary HUAM and/or Non Stress Testing applications the mother would be instructed in the use of the equipment. The FETAL ASSIST is a prescription device.
Product Code	LQK, MOH, HGM	LQK, MOH
Classification	884.2730, 884.2740	884.2730
Indication	Antenatal monitoring	Antenatal monitoring
Target Patient	Gravid patient	Gravid patient
Anatomical Site	Maternal Abdomen	Maternal Abdomen
Use/Reuse	Reusable	Reusable

Sterility	Non-sterile	Non-sterile
Fetal Heart Rate	**Sense4Baby System B+ (MSA)**	**Huntliegh Healthcare Limited Fetal Assist (K020390)**
Technology	Pulsed Doppler Ultrasound	Doppler Ultrasound
Sensors	Piezo-electric crystals	Piezo-ceramic transmitter crystals
Ultrasound frequency	1 MHz	1.5 Mhz
Ultrasound burst rep rate	3125 Hz	3200 Hz
Signal Processing	Analog to digital conversion	Analog to digital conversion
FHR sensor power source	Rechargeable battery	Rechargeable battery
FHR audio signal	Speakers (phone)	Speaker
Fetal Motion Indicator	Yes (3 levels)	Yes
Signal Quality Indicator	Yes (3 levels)	Yes
External Uterine Pressure	**Sense4Baby System B+ (MSA)**	**Huntliegh Healthcare Limited Fetal Assist (K020390)**
Technology	Relative pressure sensor (tocodynamometer)	Relative pressure sensor (tocodynamometer)
Sensor	Differential pressure sensor	Differential pressure sensor
Signal Processing	Analog to digital conversion	Analog to digital conversion
Toco sensor power source	Rechargeable battery	Rechargeable battery
Connection of toco sensor	Wireless (Bluetooth)	Cable
Physical	**Sense4Baby System B+**	**Huntliegh Healthcare Limited Fetal Assist (K020390)**
Size	25mm(H) x 95mm(W) x 75MM(D)	2" (50mm) x 10" (250mm) x 6 (150mm)
Weight	<0.2 kg	3.5 lb (1.6Kg) (including battery)
Safety	**Sense4Baby System B+ (MSA)**	**Huntliegh Healthcare Limited Fetal Assist (K020390)**
Hardware	IEC 60601 compliant	EN60601-1: 1990 compliant
Ultrasound	IEC 60601-2-37 compliant	--
EMC	IEC 60601-1-2 compliant	EN60601-1-2 : 1993 compliant
Applied Parts Type	BF	--
Biocompatible materials	Yes	--

1.4. Substantial Equivalence Discussion

The S4B System B+ (MSA) is substantially equivalent to the Huntliegh Healthcare Limited Fetal Assist (K020390) Systems based on indications for use and comparison of the functional capabilities. All of the devices are intended to provide fetal heart rate monitoring. Features common to all systems include:

- Doppler Ultrasound Technology
- Analog to digital signal conversion
- Rechargeable Batteries
- Relative Pressure Sensors

Huntliegh Healthcare Limited Fetal Assist (K020390)
The S4B System B+ (MSA) is substantially equivalent to the Huntliegh Healthcare Limited Fetal Assist System (K020390). This is based on the comparison of the indications for use and comparison of the functional capabilities. All of the devices are intended to provide fetal heart rate monitoring.

DEVICE		Comparison
Model B+ (MSA)	The Model B+ (MSA) uses Pulsed Doppler ultrasound technology to determine the fetal heart rate, and obtain indications of fetal motion.	**Equivalent** to Predicate
Fetal Assist	The Fetal Assist uses the Doppler principle for non-invasive monitoring of Fetal Heart Rate and Fetal movement.	

For this primary function, the Model B+ (MSA) utilizes scientific technology / operating principles which are identical or equivalent to the Fetal Assist. These are detailed below:

Device	Technology	Comparison
Model B+ (MSA)	The fetal heart rate is commonly measured using Doppler ultrasound devices and uterine contractions are commonly measured with a strain gauge based tocodynamometer. The Sense4Baby System Model B+ uses Piezo-electric crystals to generate the ultrasound signals and conventional technologies to measure the fetal heart rate and uterine contraction patterns. The result is a graphical overlay of both measurements that can be viewed either on a screen or on paper.	**Equivalent** to Predicate
Fetal Assist (K020390)	The Fetal Assist ultrasound transducer contains a transmitter and receiver. In use, the transducer sends out a pulsed ultrasonic signal, generated by the piezo-ceramic transmitter crystals.	

The minor differences between the S4B System B+ (MSA and the Huntliegh Healthcare Limited Fetal Assist System (K020390) do not raise new questions of safety or effectiveness. These differences will be discussed in turn below:

Ultrasound Frequency:
The Model B+ (MSA), use a frequency of 1 MHz, while the Fetal Assist (K020390) uses a frequency of 1.5 MHz. While these frequencies are similar, the lower the ultrasound frequency the better the depth pf penetration of ultrasound. The Model B+ (MSA) has a slightly deeper penetration than the Fetal Assist (K020390).

Ultrasound Burst Rate:
The Model B+ (MSA), use a burst rate of 3125Hz, while the Fetal Assist (K020390) uses a burst rate of 3200 Hz. The 3125Hz burst rate sets the rate at which 1MHz pulses are transmitted and the echoes are sampled and received. The 3200Hz sampling rate may result in a negligible increase in the resolution of the fetal heart rate (FHR) at the high end of the FHR range. This difference between the two systems does not raise any safety and effectiveness concerns.

A detailed comparison of the technological characteristics of the Sense4Baby System and the referenced predicate device is in section 5.3. No applicable performance standards have been issued under Section 514 of the Food, Drug, and Cosmetic Act for this device type. FDA Form 3654 is included in this submission to identify national and international standards used in the development and testing of the Sense4Baby System Model B+ including the following voluntary safety standards:

- IEC 60601-1:2005 + CORR.2 (2007) + A1(2012), Medical electrical equipment – Part 1: General requirements for safety.
- National deviations of IEC 60601-1: 2005, such as EN 60601-1, Ed. 3 (European Harmonized Standard), AAMI ES 60601-1, Ed. 1 (US National Standard), CSA – C22.2 No 60601-1:2008 (Canadian National Standard).
- IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-11:2010, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-2-37:2007 Medical Electrical Equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
- ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009: Biological evaluation of medical devices, Part 5- Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices, Part 10- Tests for irritation and skin sensitization.
- ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems.
- IEC 60529:1989 + A1(1999) Degrees of protection provided by enclosures (IP Code).
  Additional standards used in the development and risk analyses of the Sense4Baby System Model B+ are listed below:
- ISO14971:2007 Medical Devices- Application of risk management to medical devices.
- ISO13485:2003 Medical Devices- Quality management systems- Requirements for regulatory purposes.

1.5. Test Summary

Verification and validation activities established the performance, functionality, and reliability characteristics of the device with respect to the predicate. Testing involved sub-system, as well as system level tests. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results demonstrated substantial equivalence. Executed testing included:

- Simulated Use testing
- Hardware testing
- Predicate comparison testing
- Software testing
- Environmental testing (operating and storage)
- Mechanical testing (drop, cleaning, etc.)
- Water ingress testing (to IEC 60529)
- Shipping testing (to ASTM D4169-09)
- Formative Usability Testing
- Summative Usability Testing

1.6. Conclusion:

Therefore AirStrip Technologies, Inc. (S4B) is seeking pre-market clearance to introduce the Sense4Baby System Model B+ (MSA) maternal/fetal monitoring system into commercial distribution, with patient use as part of the indications for use. This document inclusive of its attachments contains a complete description of the Sense4Baby System Model B+ (MSA) Fetal monitoring system, a side by side comparison of the Sense4Baby System Model B+ (MSA) to the Huntliegh Healthcare Limited Fetal Assist (K020390) predicate device, a summary of all testing performed and the test results obtained. This information, when considered in its totality provides ample objective evidence that the Sense4Baby System Model B+ (MSA) has been demonstrated to be substantially equivalent to the predicate devices, and raises no new concerns related to safety or efficacy; allowing FDA to make a determination of substantial equivalence and clear the device as described for commercial distribution.

S4B conducted two separate studies to determine the ability of the user to operate the device in the home environment. These studies focused on key aspects of the system use. These basic functional aspects of the system were deemed necessary to determine the ability of the user to successfully operate the system in the home environment.

These studies (both formative and summative) provided documented objective evidence that the device was usable by lay users, even when the provided instruction materials was limited to a Quick Start Guide, with a success rate of use in the home environment that was statistically equivalent to the results obtained in the health care provider environment.