Sense4Baby, Inc.

510(k) Summary

NOV 22 2013

Submitters Name:

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Sense4Baby, Inc.
3344 N. Torrey Pines Court, Suite 100
La Jolla, CA 92037

Date of Summary:

This summary was prepared on July 1, 2013

Trade Name of the Device:

Sense 4 Baby System, Model B+

Common Name:

Fetal Monitor

Regulatory Classification: Class II (Performance standards)

Device Panel	Classification	Product Code	Description
Obstetrical and Gynecological Monitoring Devices	§884.2740.	HGM	Perinatal monitoring system and accessories

Predicate Device:

Phillips/HP Series 50XM Fetal Monitor 510(k) # K954351.

Device Description:

The Sense4Baby Model B+ 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.

Indications for Use:

The Sense4Baby System Model B+ is indicated for monitoring of maternal and fetal physiologic parameters during the antepartum period. It is to be used by health care professionals in hospitals, clinics, physicians' offices, antepartum rooms, and in the patients' home on the order of a physician.

Technological Characteristics:

The fundamental scientific technology employed in the operation of the Sense4Baby, Inc. Model B+ Fetal/Maternal Monitor is substantially equivalent to that of the Phillips/HP Series 50XM Fetal monitor.

Safety Testing (Bench):

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

- Electrical Safety
- 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+ 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

Performance Testing (Bench):

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. Performance bench 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)

Conclusion:

The performance and safety verification and validation test results demonstrate that the Sense4Baby System Model B+ is as safe and effective, and performs as well as the predicate device.

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

November 22, 2013

Sense4Baby, Inc.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street
Buffalo, MN 55313

Re: K132918
Trade/Device Name: Sense4Baby System model B+
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, KNG, HFM
Dated: November 7, 2013
Received: November 8, 2013

Dear Mark Job,

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,

Benjamin R. Fisher -S

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 (if known): K132918 Device Name: Sense4Baby System Model B+

Indications for Use:

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It is to be used by health care professionals in hospitals, clinics, physicians' offices, antepartum rooms, and in the patient's home on the order of a physician."

Prescription Use: X (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ AND/OR (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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