510(K) SUMMARY

EarlySense Ltd.

EarlySense System 2.0

Applicant's Name:

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Contact Person:

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Date Prepared:

June 16, 2013

Trade Name:

EarlySense System (Model 2.0)

Classification Name:

Breathing frequency monitor, Cardiac monitor (including cardiotachometer and rate alarm), Oximeter

Class: II

Regulation Number:

21 CFR Sec. 868.2375

21 CFR Sec. 870.2300

21 CFR Sec. 870.2700

Product Code:

BZQ, DRT, DQA

Predicate Device:

EarlySense (EverOn™1.0S) System (K120465)

Reason for Submission:

A traditional 510(k) is submitted for the hardware and software modifications made to the cleared EarlySense (EverOn™1.0S) System (K120465).

Intended Use/Indications for Use:

The EarlySense 2.0 System is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, at home, hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition. In addition, EarlySense 2.0 System can continuously monitor oxygen saturation of arterial hemoglobin (SpO2) using pulse oximetry in pediatric (ages 2 years and older), adolescents, and adults at home, hospital, or clinical settings.

Device Description

The modified EarlySense System 2.0 is similar to cleared (EverOn™1.0S) System (K120465) except for the hardware and software changes that are described below.

The cleared (K120465) EarlySense (EverOn™1.0S) System is comprised of the following components:

1. A Bed Sensing Unit based on piezoelectric sensing

2. A Bedside Unit incorporating a medical grade power supply and the following modules:

a. A Signal Sampling Module consisting of amplifiers, filters and analog to digital converter as well as a microprocessor designated to transfer the sampled data to the Signal Processing Module, and

b. A Signal Processing and Display Module.

3. An Optional Oximetry OEM module with communication interface and compatible marketed sensors.

Substantial Equivalence

The EarlySense System Model 2.0, subject of this submission, shares exactly the same intended use and indications for use with its predicate device EarlySense (EverOn™1.0S, K120465). The main technological characteristics and principles of operation are also identical to predicate device: EarlySense Model 2.0 is designed for continuous and contact-less monitoring of respiration rate, heart rate and movement in the same manner as its predicate device. The under mattress Bed Sensing Unit converts mechanical movements into an electrical signal in the same way as its predicate device.

The modifications to the cleared (K120465) EarlySense (EverOn™1.0S) were the following:

Modifications to the Bed Sensing Unit:

-Addition of the accelerometer component to the Bed Sensing Unit (which helps the user to correctly position the sensor and makes it possible to present the additional directional information also on the GUI)

-Addition of the piezoelectric polymer sensor to the already existing ceramic piezoelectric sensor (in order to increase signal in the bed exit function)

-Addition of Base Plate Handles (integrated handles on the sides of the Bed Sensing Unit to facilitate easy grasping)

Modifications to the Bedside Unit:

The Bedside Unit used in the cleared EarlySense Unit was changed to the thinner and lighter Bedside Unit (dimensional changes), which in its turn leaded to several additional hardware changes: e. g; replacement of power supply, speaker's buzzer, communication card, fan, additional USB and sensor's connectors. The software version was also updated to next version 1.0.3.

The cleared (K120465) EarlySense (EverOn™1.0S) and modified EarlySense System 2.0 are identical in the fundamental system principles and mode of operation and the presented modifications are not expected to affect the functionality of the EarlySense 2.0 System. More specifically, the introduced modifications do not constitute any significant change to the indications for use, performance specifications, or labeling.

Verification and Validation Activities:

The cleared and modified EarlySense Systems share exactly the same intended use and indications for use, the same fundamental functionality and types of components, and the same fundamental principles and mode of operation. The modifications included software and hardware modifications to the Bedside and Bed Sensing Units.

The EarlySense System 2.0 was subject to the whole range of verification and validation tests:

1. Risk analysis (See Section 21 of the current submission)
2. Software Verification and Validation (See Section 16 of the current submission)
3. Electrical safety and electromagnetic compatibility (See Section 17 of the current submission)
4. Environmental Conditions Testing (Storage, Operation and Shipping)(See Section 21 of the current submission)
5. Performance Bench Testing (See Section 18 of the current submission)

The results of the tests showed, that the modifications to the system did not affect its performance, effectiveness or safety. Therefore, it may be concluded that the modifications introduced in the EarlySense 2.0 System, individually and collectively, could not significantly affect the EarlySense System safety or effectiveness, and thus it may be considered to be substantially equivalent to the previously cleared (K120465) EarlySense System Model 1.0S.

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

December 18, 2013

EarlySense Limited
Ms. Dalia Argaman
Vice President, Regulatory Affairs and Quality Assurance
12 Tzvi Street
Ramat Gan
ISRAEL 52504

Re: K131379
Trade/Device Name: EarlySense System (Model 2.0)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: November 13, 2013
Received: November 18, 2013

Dear Ms. Argaman:

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 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. 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,

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131379

Device Name
EarlySense System 2.0

Indications for Use *(Describe)*
The EarlySense 2.0 System is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, at home, hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition. In addition, EarlySense 2.0 System can continuously monitor oxygen saturation of arterial hemoglobin (SpO2) using pulse oximetry in pediatric (ages 2 years and older), adolescents, and adults at home, hospital, or clinical settings.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S
Digitally signed by Anya C. Harry -S
DN: c=US, g=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=00113115590
Date: 2013.12.17 21:58:19 -05'00'