DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 6, 2016

EarlySense Ltd.
Ms. Dalia Argaman
VP Clinical, Regulatory Affairs and QA
12 Tzvi Street
Ramat Gan, 5250429
Israel

Re: K152911
Trade/Device Name: EarlySense Insight System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: April 4, 2016
Received: April 5, 2015

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 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,

Tina Kiang -S

for Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152911

Device Name
EarlySense InSight System

Indications for Use *(Describe)*
The EarlySense InSight System is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, in 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.

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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510(K) SUMMARY

EarlySense InSight System

I. SUBMITTER

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Date Updated: May 5, 2016

II. DEVICE

Trade Name: EarlySense InSight System
Classification Name: Breathing frequency monitor (21 CFR Sec. 868.2375)
Regulatory Class: II
Product Code: BZQ,
There were no prior submissions for the subject device.

III. DEVICES

Primary Predicate:
EarlySense 2.0 System (K131379) manufactured by EarlySense Ltd, which can be used both with under the mattress bed sensing unit and with Chair Sensing Unit (K133661)
Secondary Predicate:
Wireless 2000 PAM™3000 (K082626) manufactured by Wireless 2000
These predicates have not been subjects to a design-related recall.
Reference:
Chair Sensing Unit (K133661) can also be used with Insight Device as optional sensing unit.

IV. DEVICE DESCRIPTION

A traditional 510(k) is submitted to clear the new EarlySense InSight System. The EarlySense Insight System developed by EarlySense Ltd. is designed for continuous and contact-free measurement of Heart and Respiratory Rate. In addition, the System tracks body motion; monitors patient movement and can notify users when the patient exits the bed or the chair. The device does not have a display and is controlled from a remote control and display station by the user. The measured data on Heart Rate, Respiratory Rate, Movement and alerts are communicated to a remote station that can communicate with the EarlySense device according to predefined protocol, to be displayed to users. The Remote Control and Display Device (RCD) can be computer or central monitoring device that can communicate with the InSight Unit through predefined standard protocol through LAN or Wi-Fi and is capable to remotely access the InSight Unit and display the information received from InSight Unit. All the settings and changing of configurations is performed by the user, via a Remote Control and Display Device (RCD device). The EarlySense Insight monitoring device can notify the Remote Control and Display device, when monitored parameters excurse above or below predefined limits. The user (Healthcare practitioner) receives the information and should actively acknowledge the alert notifications and adjust monitoring parameters as required.

The EarlySense InSight device incorporates the following components:

- EarlySense InSight Unit – placed at bedside (subject of this submission)
- EarlySense Bed Sensing Unit (K131379) placed under the mattress
- Chair Sensing Unit (optional)(K133661)

V. INTENDED USE/INDICATIONS FOR USE

The EarlySense InSight Device is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, in hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense System has been

studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition.

The intended use of EarlySense InSight System is similar to its' primary predicate, EarlySense 2.0 System in all aspects, including clinical environment of usage and patient population.

EarlySense InSight has similar intended use as the cleared intended use for EarlySense System 2.0 (K131379) device that has already been cleared for usage in hospital and clinic environment for children, adolescents and adults. The intended use is also similar to the second predicate device, PAM™3000, the only difference is that in terms of patient population - the usage of the EarlySense Insight device is wider than PAM ™3000 and includes children over the 2 years old, similar to the intended use of EarlySense 2.0 device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The EarlySense InSight System shares the similar fundamental technology and functionality, similar types of components, similar intended use and indications for use with the predicate devices. The following table in details describes the similarities and differences between the submitted device and its predicate devices.

Table 5-1: Substantial Equivalence between the EarlySense InSight System and its' predicate devices

	EarlySense InSight System	**EarlySense 2.0 System**	**PAM™3000**
K_number	K152911	K131379	K082626
Product Code	BZQ	BZQ	DRT/BZQ
Regulation Number	868.2375	868.2375	870.2300/868.2375
Classification Name	Breathing Frequency Monitor	Breathing Frequency Monitor	Monitor, Cardiac (incl. cardiotachometer &rate alarm) monitor,

	EarlySense InSight System	**EarlySense 2.0 System**	**PAM™3000**
			breathing frequency monitor
Manufacturer	EarlySense Ltd.	EarlySense Ltd.	Wireless 2000
Intended Use and Indications for Use	The EarlySense InSight Device is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, in 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.	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 clinic settings.	The PAM™3000 system is intended to measure heart rate and respiration rate in adult patients, in a general care hospital environment including nursing homes. The system monitors presence or absence if a patient in bed (bed exit). The system also times the length of continuous patient motion or absence of patient motion.
Sensing Unit	**The Same** Contactless sensing unit (Piezoelectric) placed under the mattress / on the chair	Contactless sensing unit (Piezoelectric) placed under the mattress / on the chair	Ultra Wide Band motion sensor – Bed sensor Panel (BSP), placed under the bed mattress

	EarlySense InSight System	**EarlySense 2.0 System**	**PAM™3000**
	(Bed Sensing Unit submitted as part of EarlySense 2.0 System (K131379) and Chair Sensing Unit, submitted separately K133661)	(Bed Sensing Unit submitted as part of EarlySense 2.0 System (K131379) and Chair Sensing Unit, submitted separately K133661)	
Chair Sensing Unit Cover, Material	The Same 100% Polyester	100% Polyester	
SpO2 module	Not supported by InSight device	Is supported by Earlysense 2.0 - as optional module	Not used with the system
Bedside Unit	Yes (processing unit). No display and graphical user interface	Yes Includes processing unit, and graphical User interface Display.	No
Energy source	AC power source	AC power source	AC power source
Battery exist	No	Yes	No
Clinical environment of Use	Hospital, or clinic environment	Home, Hospitals, or clinic environment.	Hospital or hospital type and clinic environment
Patient Population	**Same** Children, adolescents and adults	Children, adolescents and adults	Adults
Visual and Audio Indication at bedside	Yes LEDS and Buzzer	Yes. LEDS ,buzzer and display	No
Software Application and Algorithms	Proprietary Software developed by Earlysense (Same)	Proprietary Software developed by Earlysense.	Proprietary Graphic User Interface Software on Central Computer Station

	EarlySense InSight System	**EarlySense 2.0 System**	**PAM™3000**
User Interface Display at bedside	No	Yes	No
Network Communication	Same LAN and Wi-Fi	Yes LAN and WI-FI	Yes WI-FI
Communication with Central Station	Communication with Central control and display Stations (LAN or Wi-Fi) according to standard predefined protocols	Communication with EarlySense Central Display Station (LAN and/ or Wi-Fi)	Communication with Central Computer Station (that controls operation and displays monitoring information
Patient monitoring	**Same.** Monitoring physiological parameters: - Heart Rate - Respiration Rate - Movement - Occupancy and Exit (Bed /Chair) **Does not support connection to Oxygen Saturation monitoring option and display.**	Monitoring physiological parameters: - Heart Rate - Respiration Rate - Movement - Occupancy and Exit (Bed /Chair) - Oxygen Saturation (optional external module is supported),	Monitoring physiological parameters: - Heart Rate, - Respiration Rate - Motion - bed occupancy data, patient motion
Alerts	**Same** (for parameters crossing predefined thresholds) - Heart Rate - Respiratory Rate - Motion - Bed / Chair Occupancy	(for parameters crossing predefined thresholds) - Heart Rate - Respiratory Rate - Motion - Bed / Chair Occupancy - Oxygen Saturation	- Heart Rate - Respiratory Rate Alert - Bed Occupancy - Motion
Displayed information	No Display Screen at Bedside. Monitoring data is communicated to remote control and	Parameters are displayed at bedside screen , and are communicated to	The information gathered by the system (physiological parameters and alerts) are displayed on a PC

	EarlySense InSight System	**EarlySense 2.0 System**	**PAM™3000**
	display station that allows the user to control bedside unit operation and displays monitoring data.	Earlysense Central Station	monitor using Wireless 2000's proprietary Graphic User Interface (GUI) software. The Central Computer Station (CCS) is typically placed at the nursing station.

The following similarities are found between the EarlySense InSight System and its predicate devices:

The EarlySense Insight System share the same technological principle with its predicate devices and at the high level, the subject and predicate devices are based on the same technological features:

- EarlySense InSight System's performance is based on contactless monitoring of Heart Rate, Respiration Rate and movement using piezoelectric sensors which were used and cleared in its predicate EarlySense 2.0 System- Bed Sensing Unit (K131379) and Chair Sensing Unit (K133661). The sensing units are used in exactly the same as cleared by FDA, no changes were performed.
- The Bed or Chair Sensing Unit of the EarlySense System detects motion signals (mechanical movements) in a continuous contact-less manner. These signals are converted into an electric signal, which is transferred to the InSight Unit. In the InSight Unit the electric signal is sampled, filtered and analyzed by the System software to provide the respiration rate (RR), heart rate (HR), and movement level. The system's detection algorithms (the same as those used in the predicate EarlySense 2.0 device) differentiate between large body movements, breathing movements and the cardioballistic effect, and thus compute the continuous heart and respiration rates and the body movement rate.

- The data is then transferred for display to a remote control and display device via LAN or Wi-Fi, similar to the predicate the EarlySense 2.0 System.

The following differences exist between the EarlySense InSight System and its predicate devices:

- The EarlySense InSight Unit has no display (opposite to the EarlySense 2.0 System) – the monitoring parameters and alerts can be viewed from the remote control and display system that can be placed on the nurse station. However, in this aspect, the Insight is similar to its second predicate, PAM™3000, which also has no display and no bedside unit.
- EarlySense InSight Unit does not support monitoring and display of SpO_2 measurement by external module, and in this aspect it is similar to PAM™3000, but different from EarlySense 2.0 device.
- EarlySense InSight device does not have secondary power source – a battery, similar to PAM™3000, but different from EarlySense 2.0 device.

VII. PERFORMANCE AND NON CLINICAL TESTING

The EarlySense InSight System was subject to the verification and validation tests:

1. Risk analysis
2. Software Verification and Validation
3. EMC and Safety testing
4. Full load bench testing
5. Non Clinical Testing: EarlySense Insight Performance Verification

Non-clinical tests included side by side performance testing of the InSight device vs. its predicate EarlySense 2.0. Signals from children, adolescents and adults' populations were tested. The accuracy of the InSight and EarlySense 2.0 in analyzing the signals and generating heart rate, respiration rate and motion measures were compared to results of reference device (Embla Sleep

lab. System Medcare K024322). The devices' performance was found to be similar in respect to heart rate, respiratory rate and motion measurements.

Full load bench testing was also performed to examine the communication behavior aspects of EarlySense Insight units vs. EarlySense 2.0 predicate. The results of the bench tests showed that the InSight system performance is as good as the EarlySense 2.0, and thus concluded that it is substantially equivalent to the predicate device.

Specification

Physical Characteristics

	Bed Sensing Unit	**Chair Sensing Unit**	**InSight Unit**
Dimensions	Sensor: 300 X 210 X 6.45 mm	300x210x6.45 mm	145.6 x 62 x 65.07 mm
	With handles: 420.7X210X13.8 mm		
Weight	730 g	482gr	235 ± 10 gr
Materials	ABS + Poly carbonate	ABS+ Poly carbonate Inserted into cushion: Cushion : Visco elastic (dimension- 400 x 450 x 60 mm). Cushion Cover: 100% Polyester	ABS + Poly carbonate

Electrical

Voltage Input Range	100-240 V AC, 50-60 Hz, 0.9A max

Monitoring Range

Respiratory Rate	**Heart Rate**	**Movement**
6 – 45 Br./min	30 - 170 BPM	0, L, M, H, EH

Conclusions:

The conclusions drawn from the non-clinical tests demonstrate that the device can be considered substantially equivalent to its predicate devices: EarlySense 2.0 System (K131379) and Wireless 2000 PAM™3000 (K082626).