January 4, 2018

EarlySense Ltd.
Dalia Argaman
VP Clinical, Regulatory Affairs and QA
7 Derech Zeev Jabotinsky
Ramat Gan, 525007
ISRAEL

Re: K171836
Trade/Device Name: EarlySense Bed Sensing Unit
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: November 30, 2017
Received: December 5, 2017

Dear Dalia 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171836

Device Name
EarlySense Bed Sensing Unit

Indications for Use *(Describe)*
The EarlySense Bed Sensing Unit is an accessory that is compatible with bedside units of EarlySense Systems (Models 2.0 and InSight) intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner. Environment of use for the accessory is defined as per compatible cleared bedside units labeling: EarlySense 2.0 - at home, in hospital or clinic setting and InSight - in hospital or clinic setting. The device 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.

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 Ltd.

EarlySense Bed Sensing Unit (K171836)

I. SUBMITTER:

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Date Prepared: November 30th, 2017

II. DEVICE:

Name of device: EarlySense Bed Sensing Unit
Classification Name: 21 CFR Sec. 868.2375 - breathing frequency monitor
Regulatory Class: II
Product Code: BZQ

III. Predicate Devices:

EarlySense Bed Sensing unit cleared as component to EarlySense 2.0 System (K131379) and

EarlySense Bed Sensing unit cleared as component to EarlySense InSight System (K152911).

A Traditional 510(k) is submitted for the modifications made to the cleared EarlySense Bed Sensing Unit.

IV. Device Description:

EarlySense is submitting a new model for its Bed Sensing Unit to be used with cleared EarlySense bedside unit models (EarlySense 2.0 -K131379 and EarlySense InSight - K152911) which are intended for contactless measurement of heart rate (HR), respiratory rate (RR) and motion. Similar to the cleared Bed Sensing units, the subject device is placed under the bed mattress and connected to supporting bedside unit, to allow contactless measurements of HR, RR and motion and detection of bed exit. The modification of the cleared sensing unit includes addition of two load cells elements intended to be used in the Bed Exit feature of the system. The cleared and subject device share exactly the same intended use, the same fundamental functionality and similar types of components, and the same fundamental principles and mode of operation. As also described above, the modification that includes addition of load cells is not considered to affect the system performance. The subject device is also compatible with the existing optional accessories of the cleared sensor, i.e., extension cable and solid metal plate. Utilization of extension cable is to allow placing the sensing unit under the mattress farther than 3 meters from compatible bedside units. The solid metal plate can be used for beds that have un-flat surface (such as grid like).

V. Intended Use

The subject device is intended to be used as an accessory with EarlySense System (Models 2.0 -K131379 and InSight - K152911).

VI. Indications for Use

The EarlySense Bed Sensing Unit is an accessory that is compatible with bedside units of EarlySense Systems (Models 2.0 and InSight) intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner. Environment of use for the accessory is defined as per compatible cleared bedside units labeling: EarlySense 2.0 - at home, in hospital or clinic setting and InSight - in hospital or clinic setting. The device 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.

VII. Comparison of technological characteristics with the predicate device

The cleared (AME-00200-K131379) and subject device share exactly the same intended use and indications for use. Piezoelectric sensor is the basic technological principle for both subject device and predicate Bed Sensing unit in order to monitor Heart Rate, Respiration Rate and motion in a contactless manner. The same piezoelectric sensor (located inside the both Bed Sensing units) is used to detect respiration related mechanical movement signals, heart beat-related mechanical movements and converts them into an electric signal that are sampled, filtered and transferred to the compatible EarlySense Bedside Unit where they are analyzed by algorithms to provide the respiration rate (RR), heart rate (HR), and motion measurements. The subject device consists of the following technological elements, **which are identical** to the cleared Bed Sensing Unit:

- **Piezoelectric ceramic sensing element**: detects gross body motion, heart and breathing rate motion related signals
- **Sensor Plate**: housing the piezoelectric sensing element
- **Cable and connector**: to allow connection to compatible bedside unit
- **Base plate with handles**: to allow placing the sensor under the mattress

The following **technological differences** exist between the subject device and predicate Bed Sensing Unit:

- Two load cell elements and supporting electronic circuit board added

to the base plate of the sensor. The function of the modification is to be used in the detection of the Bed Exit function.

The following table contains the summary of the substantial equivalence comparison.

Substantial Equivalence Comparison subject device to its predicate devices

	Predicate Device 1: Cleared Bed Sensing Unit (accessory to EarlySense 2.0 - K131379)	**Predicate Device 2: Cleared Bed Sensing Unit (accessory to EarlySense InSight- K152911)**	**Subject Device**
K_number	K131379	K152911	K171836
Product Code	• BZQ	The Same	The Same
Regulation	Accessory for: • 21 CFR Sec. 868.2375 Breathing frequency monitor	The Same	The Same
Environment of use/care	At home, in hospital or clinic setting	In hospital or clinic setting	Environment of use is defined as per compatible cleared bedside units labeling: EarlySense 2.0 - at home, in hospital or clinic setting and InSight - in hospital or clinic setting.
Sensor Technology	**Piezoelectric ceramic sensing element** is used to detect motion signals (mechanical movements) in a continuous contact-less manner. These signals are converted into	Identical	Identical

	Predicate Device 1: Cleared Bed Sensing Unit (accessory to EarlySense 2.0 - K131379)	**Predicate Device 2: Cleared Bed Sensing Unit (accessory to EarlySense InSight- K152911)**	**Subject Device**
	an electric signal, sampled, filtered and transferred to the Bedside Unit where they are analyzed by the Bedside unit's software (algorithms) to provide the respiration rate (RR), heart rate (HR), and motion. Bed exit signal is also detected and available.		
Bed Exit Function	Is performed by piezoelectric ceramic sensing element	Is performed by piezoelectric ceramic sensing element	Is performed by piezoelectric ceramic element as in the predicate and by addition of two load cells and supporting circuit board
Sensor "housing" / material	ABS/Polycarbonate plate	Identical	Identical
Signals Detected	Pulse rate Respiration Rate Movement Bed occupancy/ exit	Identical	Identical Pulse rate Respiration Rate Movement Bed occupancy/ exit
Technology	Detection of respiration mechanical signal and heart beat-related mechanical movements	Identical	Identical

	Predicate Device 1: Cleared Bed Sensing Unit (accessory to EarlySense 2.0 - K131379)	**Predicate Device 2: Cleared Bed Sensing Unit (accessory to EarlySense InSight- K152911)**	**Subject Device**
	(based on respiratory motion and cardioballistic effect motion)		
Patient Population	Adults, adolescents and children	Identical	Identical
Mode of Operation	Connection to EarlySense Bedside unit	Identical	Identical
Analysis (Signals processing and Display of parameters to user)	Connection to Earlysense bedside unit. Processing of signals by EarlySense proprietary algorithms which process the signals and GUI provided by bedside unit.	Identical	Identical
SpO_2 monitoring	Allows SpO_2 monitoring by utilizing an off-the-shelf module (manufactured by Nonin Medical Inc.)	The design of the device (InSight) does not allow connection to off-the-shelf SpO_2 module.	Identical to the predicate devices - the SpO_2 monitoring is performed by separate off-the-shelf module while using EarlySense 2.0 model and is not performed, while connected to InSight device. SpO_2 monitoring is not a function of the subject device
Power Source	5 Volt - received from EarlySense	Identical	Identical

	Predicate Device 1: Cleared Bed Sensing Unit (accessory to EarlySense 2.0 - K131379)	**Predicate Device 2: Cleared Bed Sensing Unit (accessory to EarlySense InSight- K152911)**	**Subject Device**
	bedside unit		
Way of connection / Communication to the Bedside Unit	Communication protocol (RS-232) and specific connector	Identical	Identical
Sensor Dimensions	420 X 210 X 14 mm	Identical	Identical
Sensor Weight	730 gr.	730gr.	760 gr
Additional sensing element	No additional sensing element in the cleared bed sensing unit	No additional sensing element in the cleared bed sensing unit	Two load cell elements were added to the sensor's base plate (housed in specially designed niches) to be used in bed exit feature, supported by additional circuit board
Method of Connection to patient	The Bed Sensing Unit is placed under the bed mattress – not touching the patient	Identical	Identical
Optional accessories	Extension cable and metal plate	The same	The same

VIII. Performance data

The subject device (as component to EarlySense System (Models 2.0 -K131379 and InSight - K152911) was subject to the verification, validation activities and bench testing, namely:

- Risk analysis
- Electrical safety and electromagnetic compatibility
- Environmental Conditions Testing (Storage, Operation and Shipping,)
- Performance Bench Testing

Risk analysis

Risk analysis was performed as for the potential hazards that are relevant to the addition of load cells to the subject device, and required testing performed as mitigations.

Electrical safety and electromagnetic compatibility

Electrical safety and EMC testing, according to the IEC 60601-1, IEC 60601-1-11, IEC 60601-1-6, IEC 62366, IEC 62304 and IEC 60601-1-2 standards. Subject device was found to comply with the requirements of the standards, when connected to compatible bedside units.

Environmental Conditions Testing

The sensing unit was subject to storage, operation and shipping testing according to standards IEC 60721-4-2:2001+A1:03 (Class 2K4) and IEC 60721-4-3:2001+A1:03 (Class 3K3). In addition, Sinusoidal vibration, Bump, Free fall test were performed according to EC TR 6071-4-2:2001+A1:03(Class 2M2). Shock test (according to IEC 60068-2-27:2008), Broad-band random vibration test (according to IEC 60068-2-64:2008), Free fall test (according to IEC 60068-2-31:2008) were performed. Subject device successfully passed all the testing. Water and solid object ingress tests were performed and sensing unit was found to be IP24 protected.

Performance Bench Testing

Bench tests were performed to verify that the heart beat and respiration signals obtained from the subject device are similar to its predicate device, and to validate that the addition of load cells do not affect signal parameters as required by the EarlySense system's algorithms, to maintain specifications. The bench testing included comparison of parameters such as: signal's amplitudes, signal to noise ratios, time domain and frequency domain comparisons, signal spectral intensities. Bench testing results showed that in all relating parameters the signals from the sensing unit were similar to the predicate sensor and all parameters were within system's algorithms specification. In addition, tests were performed to compare performance of the sensing unit to predicate sensor in providing "time to alert" for bed exit notification. Controlled experiments showed that the time to alert for bed exit notifications are similar for both sensors, thus addition of the load cells does not affect system's performance and the sensing unit is substantially equivalent to the cleared sensor.

IX. Conclusions

The non-clinical tests demonstrate that subject device is substantially equivalent to the predicate device.