K133661

510(K) SUMMARY

JUN 13 2014

EarlySense Ltd.

EarlySense Chair Sensing Unit

Applicant's Name:

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Date Prepared:

June 12, 2014

Trade Name:

EarlySense Chair Sensing Unit

Classification Name:

Accessory for Breathing Frequency Monitor

Class: II

Regulation Number:

21 CFR Sec. 868.2375

Product Code:

BZQ, DRT

Predicate Device:

- Bed Sensing Unit of EarlySense System (K120465)

Reason for Submission:

A traditional 510(k) is submitted for the addition of the optional accessory (Chair Sensing Unit) to be used with cleared EarlySense bedside units (K120465).

Intended Use/Indications for Use:

The EarlySense Chair Sensing Unit is intended to be used for continuous measurement of Respiration Rate, Heart Rate and Movement, in an automatic contact-less manner, at home, hospital or clinic setting. The sensor 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 Chair Sensing Unit can be used with bedside units that contain appropriate software (graphical interface) that can support reading and displaying EarlySense Chair Sensing Unit readings. In addition, the EarlySense 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

EarlySense is submitting a new accessory for contactless measurement of heart, respiratory rate and motion, the Chair Sensing Unit. The Chair Sensing Unit, similar to its predicate, the EarlySense Bed Sensing Unit cleared as part of previous EarlySense system submissions (K070375, K082465, K092062, K120465), is intended for continuous measurement of Heart Rate, Respiration Rate and motion while the patient is resting.

The EarlySense Chair sensing unit is comprised of the following components:

1. Sensor: that includes piezoelectric elements incorporated into a plate

2. A cushion made of foam into which the sensor is inserted into – so not to be touched by the patient.

The Chair sensing unit should be connected to a bedside unit that receives and analyzes the signals from the Chair sensing unit to measure and display heart rate, respiratory rate and motion.

Similarities and differences in technological characteristics of Chair Sensing Unit and Bed Sensing Unit (predicate)

Similarities:

- Similar piezoelectric sensor is used.

-The sensor performs similar functions as the Bed Sensing Unit does

-The way of receiving, analyzing, sampling and sending signals to the Bedside unit is similar to its predicate, Bed Sensing Unit

Differences:

-Accelerometer, rod and additional piezoelectric sensor (piezofilm) were added to the Chair Sensor

-Chair Sensor is placed under a specially-designed cushion, in order to avoid the direct contact between the patient and the sensor and to achieve the correct positioning of the sensor on the chair.

Substantial Equivalence

The EarlySense Chair Sensing Unit is similar to its predicate, the EarlySense Bed Sensing Unit. It has similar intended use and indications for use. The fundamental technology and mode of operation of the Chair sensing unit are similar as those of the Earlysense Bed Sensing unit. Similar to the cleared Bed Sensing Unit that is placed under the bed mattress and does not contact the patient, the Chair sensor is inserted into a specific cushion that mimics the bed mattress, so the chair sensor does not touch the patient. The Chair Sensing Unit performs similar functions as the Bed Sensing unit-in a contactless manner it monitors heart, respiration rate and motion. Similar to its predicate, the Earlysense Bed Sensing unit, the mechanical signals that are detected by the piezoelectric element of the sensors (Bed or Chair) are converted into an electric signal, which is then sampled and filtered and transferred to the EarlySense Bedside Unit, in order to be analyzed by the System's software to provide the respiration rate (RR), heart rate (HR), and movement rate. The system's detection algorithms differentiate between large body movements, breathing movements and the cardioballistic effect, and thus compute the continuous heart and respiration rates and the body movement.

The presented additional accessory, Chair Sensing Unit has similar functionality, the similar indications for use, technology, mode of operation and performance specifications as the Bed Sensing Unit.

Verification and Validation Activities:

The Chair Sensing Unit was subject to the following verification and validation tests to ensure correct performance:

1. Risk analysis

2. Bench Testing:

- Performance tests were performed with signals simulating physiological patient signals to evaluate the measurement and compare those to the predicate device to show equivalent performance.

- Theoretical assessment and bench tests were performed to assess the magnitude and effect of external sources of vibration and their effect on the chair sensing unit's functionality.

- Environmental testing including: Random vibration (Non-Operational test), Sinusoidal vibration (Variable Frequency Operational)

3. Complete software verification and validation testing performed to ensure proper functionality.

In addition, the Chair Sensing Unit as part of the EarlySense System was subject to complete set of testing (electrical safety, EMC and environmental testing) to ensure proper functionality.

The results of the bench tests showed, that the signals as detected by the chair sensing unit are similar to those that are detected by the predicate EarlySense Bed Sensor and thus the performance of the Chair Sensing Unit is equivalent to the performance of the Bed Sensing Unit and the performance of the chair sensor is not affected by the new design that includes insertion of the sensor into a cushion (rather than insertion of the sensor under a bed mattress). Therefore, it was concluded that the Chair Sensing Unit may be considered to be substantially equivalent to the previously cleared EarlySense Bed Sensing Unit (K120465).

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

June 13, 2014

EarlySense Ltd.
Ilana Shvorin
RA Specialist
12 Tzvi St.
Ramat Gan, Israel 52504

Re: K133661
Trade/Device Name: EarlySense Chair Sensing Unit
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: II
Product Code: BZQ, DRT
Dated: May 7, 2014
Received: May 15, 2014

Dear Ms. Shvorin:

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.

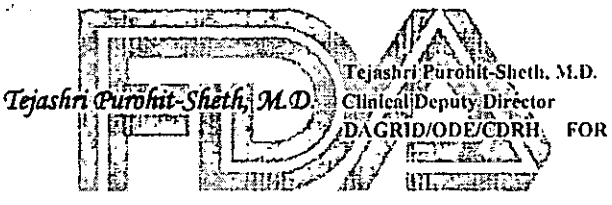
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Erin I. Keith, M.S.
Director
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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)*
K133661

Device Name
EarlySense Chair Sensing Unit

Indications for Use *(Describe)*
The EarlySense Chair Sensing Unit is intended to be used for continuous measurement of Respiration Rate, Heart Rate and Movement, in an automatic contact-less manner, at home, hospital or clinic setting. The sensor 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 Chair Sensing Unit can be used with bedside units that contain appropriate software (graphical interface) that can support reading and displaying EarlySense Chair Sensing Unit readings. In addition, the EarlySense 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)*

FDA
Anya C. Harry -S
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