K092062

MAY 2 4 2010

510(K) SUMMARY

EarlySense Ltd.

EverOn 1.0 System

7.1.1 Applicant's Name:

EarlySense Ltd.
12 Tzvi st.
Ramat Gan 52504, Israel
Tel: +972-3-7522330
Fax: +972-3-7522340

7.1.2 Contact Person:

Dalia Argaman

7.1.3 Date Prepared:

April, 2010

7.1.4 Trade Name:

EverOn 1.0 System

7.1.5 Classification Name:

Breathing frequency monitor (868.2375)

7.1.6 Classification:

Class II; Product Code- BZQ

7.1.7 Predicate Devices

EarlySense Ltd. is relying on the combination of the following predicate devices for the EverOn's movement capability substantial equivalence discussion.

- The EverOn System, cleared under K082465, breathing frequency - 868.2375, Class II; Product Code- BZQ

- Compass F10 system (MedCare) cleared under K041904 (Ventilatory Effort Recorder, Class II - Regulation number 866.2375- MNR)

- PAM 3000 (Wireless 2000 RF & UWB Technologies Ltd) cleared under K082626 - Heart Rate and Respiration rate monitor (monitor, cardiac (incl. cardiotachometer & rate alarm monitor, breathing frequency - 870 2300 & 868 2375, Class II – DRT)

7.1.8 Device Description:

The EverOn 1.0 System is designed for continuous and contact-less monitoring of respiration rate, heart rate and movement. The system automatically starts measuring whenever the patient is in bed. The EverOn can provide alert notification (audible and visible) if either parameters exceed predefined thresholds set by the user. The EverOn can also provide patient out-of-bed (Bed Exit) alert notification to the user.

The EverOn System consists of the following main components:

- A Sensing Unit placed under the mattress or mattress pad.
- A Control Unit (Bedside Unit).
- Proprietary recording and data analysis software

The under mattress Sensing Unit includes a piezoelectric sensor, which converts mechanical movements into an electric signal. The Control Unit receives the electric signals, processes them and finally calculates, logs, displays the patient's parameters, and generates alerts as per set thresholds. when needed.

7.1.9 Intended Use:

The EverOn 1.0 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 EverOn has been studied in children (weight ≥10 Kg) and adults (weight ≤111 Kg) during sleep and resting condition.

7.1.10 Performance Standards:

The EverOn 1.0 System complies with voluntary standards such as IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, AAMI / ISO 14971-1. IEC 68-2-27: Shock; IEC 68-2-6: Sinusoidal Vibration ; IEC 68-2-34 Random Vibration (Wide band)

7.1.12 Performance Data & Substantial Equivalence

The EverOn 1.0 System is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation (contact-less monitoring), performance characteristics (accuracy), intended use, etc., to the EverOn system cleared under K082465.
In addition EverOn 1.0 is substantially equivalent to its other predicates (Compass F10 system and PAM 3000 system) due to the following reasons: Both the EverOn and its predicate devices are intended for the purpose of detecting and recording physiological signals. The specific movement indication claimed by the EverOn 1.0 system is among other indications claimed by the predicates. Similar environment of use is claimed for both the EverOn and the PAM 3000 system. Both are indicated for use in the general healthcare market. The general principles of operation are also similar for both the EverOn system and its predicates in the way that all systems detect and convert physiological parameters and the body motion signals into electrical signals using sensing elements. EverOn is also similar to its predicate PAM 3000, since both systems accomplish the continuous measurement of the motion in a contact free manner. In addition the equivalence of the EverOn to its predicates regarding its capability to safely and effectively detect movement was demonstrated through a set of validation testing whereas one of the predicate was the reference device, as well as by a set of Software validation tests.

7.1.12.1 Non-Clinical Testing

In-order to demonstrate the equivalence of the EverOn 1.0 to its predicates and to demonstrate that its performance meets the requirements of its predefined acceptance criteria and its intended use the EverOn 1.0 System was subjected to the following tests:

- Electrical safety and Electromagnetic Compatibility tests
- Software verification and validation tests, to ensure the system software meet all software requirement specifications.
- Mechanical Vibration (including random and sinusoidal vibration) and Shock resistance
- Environmental tests (including operating and storage temperature and humidity conditions)

- Risk analysis activities were performed in compliance with the requirements of ISO 14971-1 "Application of risk management to medical devices" (2007).

The results of the testing indicated that the EverOn 1.0 performs according to its specifications.

7.1.12.1 Clinical Testing

The Clinical testing of the EverOn to validate its performance was performed among both children and adult populations. The system's accuracy and its capability to detect motion were compared to two reference methods: Predicate and Gold Standard.

Accuracy of the EverOn in detecting and displaying movement vs. the gold standard and the predicate are as following:

EverOn vs. Gold Standard	
Overall Accuracy - Adults	95.6%
Overall Accuracy - Children	94.8%
EverOn vs. Predicate (Compass)	
Overall Accuracy - Adults	92.3%
Overall Accuracy - Children	90.7%

No Adverse events or complications of any sort were observed during the clinical testing.

7.1.12 Conclusions

Based on the design verification and validation processes, non-clinical and the clinical testing performed it was concluded that the EverOn 1.0 System, is substantially equivalent to its predicates, without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dalia Argaman
VP, Clinical and Regulatory Affairs
EarlySense Limited
TZVI 12
Ramat – Gan
Israel 52504

MAY 24 2010

Re: K092062
Trade/Device Name: EverOn 1.0 System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ, DRT
Dated: April 22, 2010
Received: April 22, 2010

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 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):_____

Device Name: EverOn 1.0 System

Indications for Use:

The EverOn 1.0 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 EverOn has been studied in children (weight ≥10 Kg) and adults (weight ≤111 Kg) during sleep and resting condition.

Prescription Use __√__ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (Part 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number: _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

for Anthony Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092062