510(K) SUMMARY

510(K) Number K070375

5.1 Applicant's Name: EarlySense Ltd.

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Tel: +972-3-7522330
Fax: +972-3-7522340

NOV 15 2007

5.2 Contact Person: Dorit Winitz, Ph.D.

Biomedical Strategy (2004) Ltd.
7 Jabotinsky Street.
Ramat Gan 52520, Israel
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5.3 Date Prepared:

Nov., 2007

5.4 Trade Name:

EarlySense™ ES-16 System

5.5 Common Name:

Breathing frequency monitor

5.6 Classification:

Classification Name:	Breathing frequency monitor
Medical Specialty / Panel:	Anesthesiology
Product Code:	BZQ
Class:	II
Regulation Number:	868.2375

5.7 Predicate Devices:

EarlySense Ltd. is relying on the combination of the following predicate devices and a standard procedure for the EarlySense™ ES-16 System substantial equivalence discussion:

- Embla N7000 [Embla Systems, Inc.] cleared under K024322 (breathing frequency monitor, Class II-MNR); hereinafter: Embla System, supplemented with Somnologica Studio Software [Ferguson Medical] cleared as part of Embla System under K971813 (Electroencephalograph, Class II-GWQ)

- LifeShirt System with VivoLogic Analysis Software [VivoMetrics Inc.] cleared under K011903 (programmable diagnostic computer, Class II-DQK)

5.8 Device Description:

The EarlySense™ ES-16 System consists of the following main components:

- A Sensing Unit placed under the mattress pad.
- A Control Unit (Bedside Unit).
- Proprietary recording and data analysis software operating under Microsoft® Windows™ CE.

The under mattress Sensing Unit includes a piezoelectric sensor, which converts the detected respiration- and heart beat-related mechanical movements into an electric signal. The Control Unit receives the electric signals, processes them and finally calculates, logs and displays the patient's respiration rate and hear rate.

The EarlySense™ System is designed for continuous and contact-less monitoring of respiration and heart rates during sleep or resting condition, and it automatically starts measuring whenever the patient is in bed under resting or sleeping conditions. The data acquired by the System should be analyzed by a health care practitioner either in real-time (e.g. when monitoring is performed in the clinic), or off-line, after the monitoring session (e.g. when monitoring is performed at home).

5.9 Intended Use / Indication for Use:

The EarlySense™ ES-16 system is intended for continuous measurement of respiration rate and heart rate, 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 ES-16 System has been studied in children (weight ≥ 10 Kg) and adults (weight ≤111 Kg) during sleep and resting condition.

5.10 Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the EarlySense™ ES-16 System complies with the following voluntary standards:

- Medical electrical equipment- general requirements for safety. Part 1: General Requirements for Safety. IEC 60601-1(1988): +A1(1991) +A2(1995); UL 60601-1 (2003)
- Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests. EN/IEC 60601-1-2 (2001)
- Programmable electrical medical system Requirements for safety. EN/IEC 60601-1-4 (2000)
- Medical devices – Application of risk management to medical devices. ISO 14971-1 (2003)

5.11 Substantial Equivalence:

The intended use and indications for use of the EarlySense™ ES-16 System are similar to or encompassed within the intended use and indications for use of its predicate devices. In addition, the basic design and principles of operation, specifically, the use of a sensing component including a piezoelectric sensor together with a recording and processing component, which uses proprietary algorithms to calculate the desired parameters, are similar in all the devices.

A set of software, bench and clinical testing was performed in order to demonstrate the performance and accuracy of the EarlySense™ ES-16 System and to verify that it does not raise any new safety and effectiveness issues in comparison to its predicate devices. The testing included the following:

- Electrical safety and electromagnetic compatibility testing according to IEC 60601-1 (and amendments), and IEC 60601-1-2 standards.
- Software verification and validation testing
- Bench testing including a comparison to a respiration and heart beat simulator
- Clinical testing including simultaneous monitoring with the EarlySense™ System and its predicate device
- Hazard analysis including risk level and solutions performed for the entire system and for the software.

Tests results indicated that the EarlySense™ ES-16 System performs according to its specifications and accurately detects respiration rate and heart rate in comparison to its predicate devices.

5.12 Conclusion

EarlySense Ltd. believes that the EarlySense™ ES-16 System is as safe and effective as its predicate devices for its intended use and is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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EarlySense Limited
C/O Dorit Winitz, Ph.D.
Regulatory Consultant
BioMedical Strategy (2004) Limited
7, Jabotinsky Street
Ramat Gan
ISRAEL 52520

Re: K070375
Trade/Device Name: EarlySense™ ES-16 System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: November 5, 2007
Received: November 7, 2007

Dear Dr. Winitz:

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.

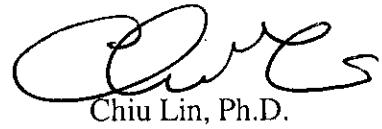
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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

510(k) Number (if known): K070375

Device Name: EarlySense™ ES-16 System

Indications for Use:

The EarlySense™ ES-16 system is intended for continuous measurement of respiration rate and heart rate, 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 ES-16 System has been studied in children (weight ≥ 10 Kg) and adults (weight ≤111 Kg) during sleep and resting condition.

Prescription Use (Part 21 CFR 801 Subpart D)	√	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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