



Food and Drug Administration
10903 New Hampshire Avenue
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August 31, 2015

Earlysense Ltd.
Dalia Argaman
VP Clinical and Regulatory Affairs
12 Tzvi St
Ramat Gan, 5250429, Israel

Re: K151006

Trade/Device Name: Earlysense Central Display System (CDS)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, MWI
Dated: June 1, 2015
Received: June 4, 2015

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.

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151006

Device Name

EarlySense Central Display Station (CDS)

Indications for Use (Describe)

The EarlySense Central Display System is intended to provide remote central monitoring and display of information as recorded by multiple EarlySense bedside units, on a central remote screen. The system can be used in hospitals or hospital type and clinic environment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

EarlySense Central Display System (CDS)

I. SUBMITTER

EarlySense Ltd.
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Ramat Gan 5250429, Israel
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Fax: +972-3-7522340
Contact Person: Dalia Argaman
E-mail: Dalia.Argaman@EarlySense.com
Date Prepared: August 12, 2015

II. DEVICE

Device Common/Trade Name: EarlySense Central Display System (CDS)
Classification Name: System Network and communication, physiological monitor (21 CFR Sec. 870.2300)
Regulatory Class: II
Product Code: MSX, MWI

III. PREDICATE DEVICES

Primary Predicate:
EarlySense Central Display Station, K121885
Secondary Predicate:
Connex Central Station, K132807
These predicates have not been subjects to a design-related recall.

IV. DEVICE DESCRIPTION

A traditional 510(k) is submitted to clear the updated Central Display Station System with the new software version 1.1.2.2

The EarlySense Central Display System (CDS) is a system which includes EarlySense developed application software, installed on standard off-the-shelf PC computer with a computer screen. The system also uses standard off-the shelf communication and IT hardware.

The CDS is intended to communicate with multiple EarlySense Bedside monitoring devices (cleared as K131379 and K120465), in order to display the information as it is monitored on the bedside units on a central remote screen. The users can access the user interface of the individual bedside units via the CDS's screen and view or adjust bedside units' parameters, e.g. change settable parameters, such as alert thresholds.

The communication is performed through TCP/IP protocol, either via standard wired or via wireless LAN communication. The transmitted information from Bedside Unit to CDS and backwards includes alert information and physiological parameters (such as patient in / out of bed status, heart rate, respiration rate, motion rate and SpO₂, if monitored at bedside unit, as well as room and bed number, etc.). The CDS can also format the alert information as obtained from Bedside units into a message that can be transmitted to external devices that can communicate with the CDS via standard TCP/IP port. In addition, a possibility to remotely view the CDS screen from a tablet or additional PC computer exists.

The accessories that can be possibly used with CDS system include:

- Computer Screen
- Keyboard and mouse
- Additional hallway LCD/LED screen
- External communication devices, like: pagers, etc.
- Tablet or additional PC computer (to remotely view the CDS computer screen)

V. INTENDED USE/INDICATIONS FOR USE

The EarlySense Central Display System is intended to provide remote central monitoring and display of information as recorded by multiple EarlySense bedside units, on a central remote screen. The system can be used in hospitals or hospital type and clinic environment.

The Indications for Use statement of the EarlySense Central Display Station (CDS) is similar to its predicate devices: the modified EarlySense CDS is intended for remote view of the EarlySense bedside units monitoring data and it also allows to adjust the bedside units settable parameters by allowing remote view of the user interface of individual bedside units and adjusting the settable parameters from afar. These features were not present in the previous cleared version of the CDS, but are present in the secondary predicate, Connex Central Station, K132807, that is intended for central monitoring of patient data and alarms.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The modified EarlySense CDS Systems share the similar fundamental functionality, the similar principle of operation, similar types of components, similar intended use and indications for use with the predicate devices.

The modified EarlySense Central Display Systems 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:

- Similar to its predicates, the modified CDS is a software application that is developed by EarlySense and is installed on Off-the-shelf hardware (computer).
- Modified CDS system and its predicates are used for remote central monitoring and display of information as recorded by Bedside units.
- System hardware components are similar for all three systems and include: Standard PC with monitor, mouse, screen,

- Only the software is developed and produced by the manufacturers in modified CDS and its predicates, all the other parts of the system are bought off-the-shelf
- Modified CDS and its cleared CDS predicate remotely display and monitor exactly the same physiological parameters, such as: Heart Rate, Respiration Rate, SpO2, motion and bed exit features
- Communication with the Bedside units is performed in exactly the same way as in cleared device, through LAN and wireless LAN
- Modified and cleared CDS systems do not perform analysis of data, but only duplicate the data received from Bedside units
- EarlySense and its predicate devices are used in the same clinical environments- hospitals or hospital type and clinic environment

The following technological differences exist between the modified EarlySense CDS and its predicate devices:

- Modified CDS is able to remotely access separate Bedside units and adjust bedside unit's settable parameters from remote station. The new feature, didn't exist in cleared EarlySense CDS, but capability of adjusting bedside units parameters exists in Connex System

VII. PERFORMANCE DATA

The modified EarlySense CDS System was subject to the whole range of verification and validation tests:

1. Risk analysis (See Section 16 of the current submission)
2. Software Verification and Validation (See Section 16 of the current submission)
3. Performance Bench Testing (See Section 18 of the current submission)

The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate devices: EarlySense Central Display Station (K121885) and Connex Central Station, (K132807).