510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k102063

B. Purpose for Submission:
A new 510(k) for a diabetes management software accessory to cleared blood glucose meters

C. Manufacturer and Instrument Name:
Health-e-Connect System

D. Type of Test or Tests Performed:

Diabetes data management system

E. System Descriptions:

1. Device Description:

The ALRT Health-e-Connect System (HeC) is an internet based blood glucose monitoring system that allows healthcare providers and patients the opportunity to review, analyze and evaluate the efficacy of a diabetes management program.

The Health-e-Connect System is comprised of a home based application, legally marketed blood glucose meters (FreeStyle Freedom, FreeStyle Feedom Lite, FreeStyle Lite, Precision Xtra, Breeze2, Contour, OneTouch Ultra2, OneTouch UltraMini, Aviva, Compact Plus glucose meters) and a server.

The Health-e-Connect Programmer is a PC based application software used to register a patient's glucose meter with the Health-e-Connect System and upload historical patient blood glucose level data to Health-e-Connect system's web-based servers. The home based application software collects data from blood glucose meters and transmits the data over the home's existing internet connection where it is uploaded to the Health-e-Connect System's web-based servers.

The server is a web-based application that collects, stores and displays historical patient blood sugar levels. It also allows patients, healthcare providers, patient relatives and other healthcare providers involved in the case to send messages to each other and share patient information. This communication is retrospective and not a real- time alert or alarm. The Health-e-Connect System is a tool to monitor patients remotely and motivate them through notifications.

2. Principles of Operation:
   The operating system requirements for the Health-e-Connect System are: Windows XP, Windows Vista 32 bit and 64 bit, or Windows 7.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?
   Yes__X__or No _____.

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission:
   Yes _____ or No __X__.

4. Specimen Identification:
   Specimen identification is based on time and date of testing

5. Specimen Sampling and Handling:
   Data transmission from glucose meters using capillary whole blood samples

6. Calibration:
   Glucose meter specific. See statement below under section J.

7. Quality Control:
   Glucose meter specific. See statement below under section J.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes__X__or No _____.

F. Regulatory Information:

1. Regulation section:

   21 CFR § 862.1345 Glucose Test System
   21 CFR § 862.2100 Calculator/Data Processing Module for Clinical Use

2. Classification:

   Class II, I (respectively)

3. Product code:

   NBW, Blood Glucose Test System, Over-the-Counter
   JQP, Calculator/Data Processing Module for Clinical Use

4. Panel:

   75 (Clinical Chemistry)

G. Intended Use:

1. Indication(s) for Use:

   The Health-e-Connect System is intended for use in the home and clinical settings by people with diabetes and healthcare providers as an aid in the review, analysis and evaluation of historical glucose test results and associated usage data in support of an effective diabetes management program.

2. Special Conditions for Use Statement(s):
   None

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Express MD Solutions, LLC; Electronic House Call System; k090801

2. Comparison with Predicate Device:

Item	Candidate Health-e-connect System	Predicate Electronic House Call System (k090801)
Intended Use	The Health-e-Connect System is intended for use in the home and clinical settings by people with diabetes and healthcare providers as an aid in the review, analysis and evaluation of historical glucose test results and associated usage data in support of an effective diabetes management program.	Same
Data Sources	Electronic upload of data from supported blood glucose meters and manual entry of data	Same
Compatibility	For use with the supported glucose meters	Same

I. Special Control/Guidance Document Referenced (if applicable):

No standards cited

J. Performance Characteristics*:*

1. Analytical Performance:

   The performance characteristics listed below as applicable, were presented in the specific glucose meter clearances under (k051839, k070850, k092602, k010553, k053529, k061118, k060470, k062347, k081389, k043474).

   a. Accuracy:

   See above statement under section J.

   b. Precision/Reproducibility:

   See above statement under section J.

   c. Linearity:

   See above statement under section J.

   d. Carryover:

   See above statement under section J.

   e. Interfering Substances:

   See above statement under section J.

2. Other Supportive Instrument Performance Data Not Covered Above:

   a) The sponsor conducted bench testing using all 10 claimed glucose meters: FreeStyle Freedom, FreeStyle Feedom Lite, FreeStyle Lite, Precision Xtra, Breeze2, Contour, OneTouch Ultra2, OneTouch UltraMini, Aviva, Compact Plus. The testing verified completeness and accuracy of blood glucose value transfer, data rollover, correct time stamps, serial number and model, and HeC identified flags such as control solutions used. The study confirmed the ability of the HeC System to capture and record glucose data accurately when transferred from each of the claimed glucose meters.

   b) The usability study consisted of three components: 1) 22 lay-users with varying demographics (age, sex, and education level) were included in a usability study for electronically uploading data from glucose meters. Following the study the study participants also completed a questionnaire in

response to whether the data transmission feature is easy to use. 2) 2 health care professionals completed surveys following the study. 3) 28 study participants with varying demographics (age, sex, and education level) performed manual data entry for at least 2 days worth of data. These participants completed a survey following the study. The sponsor concluded that the user's responses indicated that data transmission function was easy to operate by following the instructions provided with the system.

c) The following documentation related to the software was reviewed and found to be acceptable: level of concern, software description, device hazard analysis, software requirements specifications, software design specification, software development environment description, and verification and validation testing.

d) The sponsor performed a readability study and obtained a Flesch-Kincaid Grade Level Score of 7.5 for the User Manual. The readability of the labeling was also assessed as part of the usability studies and surveys.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.