

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k101371

**B. Purpose for Submission:**

New 510(k) for diabetes data management software accessory for use with the On Call® Plus Glucose Meter (k090057)

**C. Measurand:**

Whole blood glucose

**D. Type of Test:**

Data management system

**E. Applicant:**

Acon Laboratories, Inc.

**F. Proprietary and Established Names:**

On Call Plus Diabetes Monitoring Software

**G. Regulatory Information:**

1. Regulation section:

21CFR Sec.- 862.1345-Glucose test system.

21CFR Sec.- 862.2100-Calculator/data processing module for clinical use.

2. Classification:

II, I

3. Product code:

NBW - System, Test, Blood Glucose, Over The Counter

JQP - Calculator/Data Processing Module, For Clinical Use

4. Panel:

Chemistry – 75

**H. Intended Use:**

1. Intended use(s):

See Indication(s) for use below

2. Indication(s) for use:

The On Call® Plus Diabetes Software is an optional software accessory to be used with the On Call® Plus Glucose Meter for transferring data to a computer and organizing it in tables and graphs to be used at home and by health care

professionals. The software does not recommend any medical treatment or medication dosage level.

3. Special conditions for use statement(s):

Over-the-counter use

4. Special instrument requirements:

On Call® Plus Glucose Meter

**I. Device Description:**

The On Call® Plus Diabetes Monitoring Software is for downloading glucose data from the On Call Plus Glucose meter to a PC through an USB to RS232 TTL level cable or RS232 to RS232 TTL level cable, with tracking and trending capabilities of glucose measurements.

The Diabetes Data Management Software is intended to be used in a clinical setting with multiple patients by a healthcare professional, or directly by the patient.

The user has the choice to install either a personal “Home” or “Professional” version. In the “Home” version, glucose results are assembled for a single user. In the “Professional” version, the software user can configure a database with multiple providers and patients. The number of providers, patients and data points is limited only by the computer’s capabilities.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Bayer Healthcare, Glucofacts® Delux Diabetes Management Software

2. Predicate 510(k) number(s):

K091820

3. Comparison with predicate:

Features	On Call® Plus Diabetes Monitoring Software	Glucofacts® Delux Diabetes Management Software (K091820)
Similarities		
<u>Intended use</u> <u>/Indication(s) for use</u>	The On Call® Plus Diabetes Software is an optional software accessory for transferring data from glucose meter to a computer and organizing it in tables and graphs to be used at home and by health care professionals. The software does not recommend any medical treatment or medication dosage level.	Same
COM Ports scan	Automatic scan for connected ports	Same
Multiple patients	Can list data for multiple patients	Same
Data list/ Summary report	List of all readings inside selected time frame	Same

Features	On Call® Plus Diabetes Monitoring Software	Glucofacts® Delux Diabetes Management Software (K091820)
Reports and charts	Data List, Log Book report, Standard Day report, Trend report, Pie charts	Same
Target levels	High, low, hyper and hypo glucose target levels can be changed	Same
Time periods	Daily time periods can be changed	Same
Units of measure	Can choose either mg/dL or mmol/L mg/dL is default	Same
Data Base	Can Set up multiple patient data bases	Same
Differences		
Change Meter settings	Does not allow change to meter settings through the Diabetes Monitoring Software	Allows target range, alarm sounds and optional level changes to supported meters through the Management Software
Operating System	Microsoft Windows 2000, XP Home/Professional, Vista, windows 7	Microsoft Windows XP, Vista or Mac OS 10.5.7 or later (Mac is only an option with the Contour USB meter)
Associate a meter to a person	No association	Software can be set to recognize meters and associate them to specific patients
Standard week report	No Standard Week report	A graph that displays all readings by day overlapping all the days on a one week graph
Average Week	A bar graph that averages all readings for each day by day of the week, Sunday through Saturday and before and after meals.	No average week report
Average Day	A bar graph that averages all readings for each day by time slot and before and after meals.	No average day report
Password	Allows providers accounts to be password protected	Does not have password protection on the software
Providers	Allows for multiple providers each with their own data base of patients	Does not have providers but does allow for multiple databases

**K. Standard/Guidance Document Referenced (if applicable):**

- ISO 14971:2007, Medical devices - Application of risk management to medical devices.
- IEC 62366, Medical devices - Application of usability engineering to medical devices.
- IEC 62304 Ed. 1.0, Medical device software - Software life cycle processes.

**L. Test Principle:**

Data Transmission of whole blood glucose data from glucose meter

**M. Performance Characteristics (if/when applicable):**

The below performance characteristics as applicable, were presented in specific glucose meter clearance under k090057

1. Analytical performance:
  - a. *Precision/Reproducibility:*  
See above statement under section M.
  - b. *Linearity/assay reportable range:*  
See above statement under section M.
  - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*  
See above statement under section M.
  - d. *Detection limit:*  
See above statement under section M.
  - e. *Analytical specificity:*  
See above statement under section M.
  - f. *Assay cut-off:*  
Not Applicable
2. Comparison studies:
  - a. *Method comparison with predicate device:*  
See above statement under section M.
  - b. *Matrix comparison:*  
Not Applicable
3. Clinical studies:
  - a. *Clinical Sensitivity:*  
Not Applicable
  - b. *Clinical specificity:*  
Not Applicable
  - c. *Other clinical supportive data (when a. and b. are not applicable):*  
Not Applicable
4. Clinical cut-off:  
Not Applicable
5. Expected values/Reference range:  
See above statement under section M.

**N. Instrument Name:**

On Call Plus Diabetes Monitoring Software

**O. System Descriptions:**

1. 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

2. Software:

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

Yes  X  or No \_\_\_\_\_

Pentium or equivalent processor, USB or RS-232 9-pin serial port, 128 MB memory, 70 MB hard drive space, minimum 800 x 600 display, CD-ROM drive

Microsoft Windows 2000, XP Home/Professional, Vista, windows 7

3. Specimen Identification:

Specimen identification is based on data transmitted from the meter.

4. Specimen Sampling and Handling:

Data transmission from glucose meters using capillary whole blood samples

5. Calibration:

Glucose meter specific See above statement under section M.

6. Quality Control:

Glucose meter specific See above statement under section M.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

A study to verify the accuracy of data transmission from the On Call Plus Blood Glucose Monitoring Meter to the On Call Plus Diabetes Monitoring Software was conducted. The data management system was challenged under the conditions in which it is intended to be used in a professional health care setting.

20 meters were used for the study each with a full memory of 300 readings. Data stored on the meters incorporated a range of dates and values and included out of range readings for both high and low and in range data including readings marked as controls.

This study verified that the data transmitted to the PC from the meters was accurate and that the data was accurately manipulated by the software 100% of the time.

In addition, 50 participants with varying demographics (age, sex, and education level) were included for individual consumer use and multiple patient use with health care provider using both the Home Edition and Professional Edition. The user guide was used in the study (Flesch Kincaid Grade Level 8.3). Participants were required to install the software on a computer, download meter data and use the various features of the program. 96% of the participants evaluated the overall easy of use for the program as OK or above, on a scale for 1 – 5 where 1(very hard) 3 (OK) and 5 (very easy).

**Q. Proposed Labeling:**

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

**R. Conclusion:**

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