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

A. 510(k) Number:
k093819

B. Purpose for Submission:
ARKRAY is seeking clearance for the ARKRAY Diabetes Data Management Software as an accessory for use with ARKRAY blood glucose meters

C. Measurand:
Whole blood glucose

D. Type of Test:
Data management system for ARKRAY OTC whole blood glucose meters

E. Applicant:
ARKRAY Factory USA, Inc

F. Proprietary and Established Names:
ARKRAY Diabetes Data Management Software (SMBG Viewer)

G. 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, Class I
3. Product code:
   NBW, CGA, JQP
4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:
1. Intended use(s):
   See Indication(s) for use below.

2. Indication(s) for use:
   ARKRAY Diabetes Data Management Software:

   The ARKRAY Diabetes Data Management Software (SMBG Viewer) is an optional accessory for use with ARKRAY blood glucose meters with data management capabilities. The ARKRAY Diabetes Data Management Software transfers data from the meter's memory into a computer for enhanced data management. The ARKRAY Diabetes Data Management Software is intended for use in home and clinical settings to assist people with diabetes and their health

care professionals in review, analysis and evaluation of historical blood glucose test results to support diabetes management.

3. Special conditions for use statement(s):
   Over-the-counter use

4. Special instrument requirements:
   ARKRAY blood glucose meters such as GLUCOCARD 01 Meter (k073416), X-METER (k063771), PocketChem EZ (k063068), EasyPRO Plus (k063068), PocketChem EZ (k090653), and GLUCOCARD® Vital™ (k091102).

I. Device Description:

The ARKRAY Diabetes Data Management Software is an optional accessory for use with ARKRAY blood glucose meters with data management capabilities. The subject device consists of a USB data transfer cable and software. The system allows the user to download blood glucose results from their glucose meter to their computer, maintain a history of their glucose test results, and convert them into graphs, charts and reports. The software does not recommend any medical treatment or medication dosage level.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   GlucoBalance™ Data Management Software,
2. Predicate 510(k) number(s):
   k022545
3. Comparison with predicate:

Device Characteristic	Predicate: GlucoBalance	New Device: SMBG
Indications for use	For use in home and clinical settings to assist people with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support diabetes management.	Identical
Installation of Program	Installed using a CD	Identical
Package Contents	Software and electronic instructions for use	Identical
Capable of uploading data from various devices	Software driver must be uploaded on the device or installed on PC	Identical
Software use indications	Home or multi-patient use setting	Identical
Deleting results	No	Yes

Language capabilities	English	Identical
Customizable schedule	Yes	Identical
Search patient capability	Yes	Identical
Clock format	12 hour clock format	Identical
Date format	Month/day/year only	Identical
Auto-detect COM port	No	Identical
Technical Support	Yes	Identical
System Components	Software and cable connection between meter and user's PC	Identical
Ability to export glucose test result information	Yes	Identical
Copy database to separate file	No	Yes
Ability to access DMS program via icon or explorer	No	Yes
Result type display	Choice of mmol/L or mg/dL	mg/dL only
Software Platform	Microsoft Windows 95, 98, NT, or 2000	--Windows 2000 Professional/ XP Home edition / XP Professional, Windows Vista (32 bit edition only)
Hardware Requirements	--200 MHz Pentium class processor, -- 32 MB RAM for Windows 95, or 98, 64 MB RAM for Windows NT or 2000, --20 MB of free hard disk space, --Floppy or CD ROM drive, -- Available serial port.	--Pentium 100MHz or more (recommend Celeron 450MHz or more), --32 MB or more (recommend 128 MB or more), -- 40 MB disc space ore more (recommend 100 MB or more) --CD ROM drive, -- Available USB port.
Reports/Graphs Generated	--Histograms, --Log Book, --Modal Day, --Pie Charts, --Statistics, --Trend Chart	Identical
Report Type: Test Frequency	Yes	No

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

ISO 14971 Medical Devices – Application of Risk Management to Medical Devices 2007

L. Test Principle:

Data Transmission of whole blood glucose data from glucose meters.

M. Performance Characteristics (if/when applicable):

The below performance characteristics as applicable, were presented in specific glucose meter clearances under k073416, k063771, k063068, k063068, k090653, and k091102.

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):
     See above statement under section M.

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:
   See above statement under section M.

N. Instrument Name:

ARKRAY Diabetes Data Management Software (SMBG Viewer)

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__

   Operating systems -Windows 2000 Professional/ XP Home edition / XP Professional, Windows Vista (32 bit edition only)

2. Software:

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

   Yes ___X____ or No _____

3. Specimen Identification:

   There are two options for data transmission; 1.) Personal option, where the data management system is dedicated to one patient; 2.) Multiple patient option where the data management system handles multiple patients.

   The difference in the options is for the multiple patient option the patient is selected prior to results being transmitted from the meter.

   Specimen identification is based on time and date of testing.

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:

ARKRAY conducted bench testing to demonstrate data accuracy transmission for each meter stated in H. 4., special instrument requirements, above. Meter flags/functions were tested such as control solution, DEL (or!), and temperature warning to verify the information properly downloads from the meters to the data management software. Memory data rollover was also tested by adding four (4) data points to meters that were pre-loaded with full memory. Test results show that all glucose values, flags, date, and time properly downloaded from the meters to the software. Memory data rollover also functioned properly where the new glucose values replaced the oldest glucose values.

In addition, two studies each intended to assess personal lay users and professional healthcare users in the setup and use of on ARKRAY's Diabetes Data Management Software were conducted. The first study included 31 personal lay users and 5 professionals and the second study included 45 personal lay users and 10 professionals. The two studies evaluated a combined, seventy-six (76) diabetic adult consumers and fifteen (15) healthcare professionals who work with diabetics.

The GLUCOCARD X-METER, GLUCOCARD® Vital™, and PocketChem EZ Meter have different user interface. The PocketChem EZ has identical user interface as the, GLUCOCARD 01, Easy PRO Plus, and EasyPro Plus.

76 Personal lay users were given the software program on CD, operating manual, step by step user instructions, a computer and printer, an ARKRAY blood glucose meter with a USB cable and the study questionnaires. They were instructed to:

1. Install the software program as directed in the operating manual.
2. Start/access software program.
3. Enter User Information
4. Download and save data from the glucose meter.
5. Access and view information in logbook.
6. Enter user health information (carbohydrates and exercise)
7. View and print graphs and reports.
8. Export CSV files.
9. Exit software program.

10. Complete “Ease of Use” and “Performance” Questionnaires.

15 Professional users were given a copy of the software program on CD, operating Manual, step by step user instructions, computer, an ARKRAY blood glucose meter with a USB cable and the study questionnaires. Using simulated patient data they were instructed to:

1. Install and start the software program as instructed in the operating manual.
2. Enter patient preferences and profile (name, target ranges, patient demographics, printer preferences, time block settings …).
3. Enter user health information (carbohydrates and exercise).
4. Download and save data from the blood glucose meter.
5. View and print graphs and reports.
6. Import and export CSV files.
7. Enter “Other Data” (HbA1c).
8. Exit software program.
9. Complete “Ease of Use” and “Performance” Questionnaires.

Personal lay users rated ARKRAY's Diabetes Data Management Software Program at 100% for overall program as easy or somewhat easy. There were no users that rated the software program as somewhat difficult or difficult.

Overall, professional health care users rated ARKRAY Diabetes Data Management Software Program at 100% as easy or somewhat 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.