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

A. 510(k) Number:
k110709

B. Purpose for Submission:
New 510(k) for diabetes data management software accessory for use with compatible glucose meters such as ARKRAY Glucocard Vital Blood Glucose Meter (k091102).

C. Measurand:
Whole blood glucose

D. Type of Test:
Diabetes data management system

E. Applicant:
ARKRAY Factory USA, Inc.

F. Proprietary and Established Names:
ARK Care™ Diabetes Management System

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:
   Class II and I, respectively
3. Product code:
   NBW - System, Test, Blood Glucose, Over the Counter
   CGA - Glucose Oxidase, Glucose
   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 ARKRAY Diabetes Management Software is an optional accessory for use with compatible blood glucose meters, such as ARKRAY Glucocard Vital Blood Glucose Meter with data management capabilities. The ARKRAY Diabetes Management Software transfers data from the meter's memory into a secured sever for enhanced data management. ARKRAY ARK Care™ Diabetes

Management System is intended for use in home and clinical settings via the internet to assist people with diabetes and their healthcare professionals in uploading, storing, analyzing, and communicating about historical blood glucose test results and other biological statistics to support improved diabetes management.

3. Special conditions for use statement(s):
   Over the Counter (OTC) use
4. Special instrument requirements:
   ARKRAY Glucocard Vital Blood Glucose Meter

I. Device Description:

The ARK Care Diabetes Management system serves as an interface between the software in compatible glucose meters and a general purpose health management database to assist in the review, analysis and evaluation of blood glucose test results. ARK Care is a secure system designed for home use and professional healthcare settings.

The purpose of the electronic diabetes management system is to help users and healthcare teams manage blood glucose information to help with diabetes management. After the user transmits and stores blood glucose data to the secure database, the ARK Care system allows family members and/or healthcare professionals to view and monitor the user's data and reports. Family and healthcare team members must receive permission from the primary user and create a password protected login before viewing data and allows for secure communications. The user and approved healthcare team members can view the blood glucose data in different formats such as logbooks, charts, and graphs. The data can be viewed through selected time intervals and these intervals can be compared over time to track disease management. The subject can also enter and track other health-related information such as body weight, blood pressure, lab values, and exercise activities. Groups of profiles can be queried for bulk reporting on data related to tracking and trending of outcomes, supporting diabetes disease management in individuals and in managed care organizations.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   MyCare Team, MCT Diabetes
2. Predicate 510(k) number(s):
   k073699
3. Comparison with predicate:

Device Characteristic	New Device: ARK Care Diabetes Management	Predicate: MCT Diabetes

Device Characteristic	New Device: ARK Care Diabetes Management	Predicate: MCT Diabetes
Indications for Use Statement	ARKRAY ARK Care Diabetes Management System™ is intended for use in home and clinical settings via the internet to assist people with diabetes and their healthcare professionals in uploading, storing, analyzing, and communicating about historical blood glucose test results and other biological statistics to support diabetes management.	Same
Intended Use	Home use or Clinical Assist diabetics, families, and professionals in management of blood glucose Support diabetes management Single or multi-patient use Same	Same
Data Source	Compile data from multiple different brands of glucose meters for display in one place on user's personal computer	Same
Software Use	Single (individual) or multiple user (clinical) settings	Same
Use in Clinic	Patient list available	Same
Report types	Logbook Readings Line Chart Average Bar Chart Percentage Pie Chart Percentage Reading by Time of Day	Same
Special Glucose Monitor Instrument Requirements	Wide Range of Supported meters are available; As additional software protocols are obtained and devices are validated, capabilities will be broadened to include other blood glucose meters.	Same
User's Personal Computer (PC)	Windows Vista (32 and 64 bit) Windows XP-XP Home Edition & XP Professional (32 bit) Windows 7 (32 and 64 bit)	Windows 98 Second Edition (SE), Windows 2000 and Windows XP Home and Professional
Requirements	• 600 MHz Intel Pentium II or equivalent • Minimum 128MB RAM 100-200MB RAM used during installations and 100MB used after installation.	Same Same

Device Characteristic	New Device: ARK Care Diabetes Management	Predicate: MCT Diabetes
	• CD ROM Drive • BGM Manufacturer's required cable. • Installed from website	Same Same Same
Technical Support	Yes	Same
User's Manual	Available on Internet while using program ("Help System") Hard copy user manual available	Same
Auto-detect COM port	Yes	Same
Installation of program	Installed from internet link	Same
Required data on patient entry includes patient ID, name, address, ect.	Yes	Same
Physician Information	Multiple individuals	Same
Diabetes educator information	Multiple individuals	Same
Types of information that can be manually entered	Insulin list, medication list, exercise, blood pressure data, laboratory results, meals	Same

K. Standard/Guidance Document Referenced (if applicable):
IS0l4971 - Medical Devices-Application of Risk Management to Medical Devices

L. Test Principle:
ARK Care Diabetes Management software is an accessory to compatible meters, which use specific test principles such as in the ARKRAY Glucocard Vital Blood Glucose Meter (k091102)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Presented in k091102
   b. *Linearity/assay reportable range:*
      Presented in k091102
   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
      Presented in k091102
   d. *Detection limit:*
      Presented in k091102
   e. *Analytical specificity:*

Presented in k091102

f. Assay cut-off:
Presented in k091102

2. Comparison studies:
   a. Method comparison with predicate device:
   Presented in k091102
   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):

Thirty eight (38) diabetic adult consumers and six (6) healthcare professionals were recruited and screened for study inclusion criteria. Inclusion criteria for participants included that the user was capable of using a computer independently and had at minimum basic computer skills. Personal Users must be a Type 1 or Type 2 diabetic who is actively testing their blood glucose. Professional Users needed to have a degree in a healthcare field that may require interaction with diabetic persons.

Users were given the use of a laptop with the ARK Care website open, a preloaded meter with glucose and control solution values, the User Guide and a set of user (Personal and Professional) instructions to complete study tasks. Program evaluation was measured by completing ease of use and performance questionnaires

The Personal User participants were asked to:

1. Enroll as a patient
2. Navigation Overview
3. Create a Care Team
4. Glucose Meter Upload
5. Manually add Medication, Lab results, Meals and Insulin using My Data Logbooks
6. View Detail Readings chart in My Charts
7. View and Print Average Readings charts in My Charts
8. View Total View chart in My Charts
9. Sign Out of ARK Care site
10. Rate the program by completing questionnaires

The Professional participants were asked to:

1. Enroll from an email invitation
2. Register as a Care Team Member

3. From My Data -> Alerts view your team member's information
4. Navigation overview
5. Display Blood Glucose Logbook
6. Display Medication Log
7. Display and Print Lab Test Results
8. Display Meal Log
9. Display Insulin Log
10. Display Total View interactive chart
11. Under My Information -> Notifications set to Daily updates and save
12. Sign Out of ARK Care site
13. Rate the program by completing questionnaires

The scores of "Ease of Use" and "Performance" questionnaires were both over 99% passing. Sixty-eight percent (68%) of Personal Users would use this software program to help manage their diabetes and one-hundred percent (100%) of Professional Users would use this program to assist in managing their patient's diabetes.

The scores for pass/fail criteria of both groups exceeded 80% and 70% required for the acceptance criteria. The clinical data demonstrated that the ARK Care Internet-Based Diabetes Management System for diabetics is easy to use for both personal and professional users. The software performed as expected during the course of the study.

4. Clinical cut-off**:**
   Not Applicable
5. Expected values/Reference range:
   Presented in k091102

N. Instrument Name:

ARKRAY Diabetes Management 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__

Windows Vista (32 & 64 bit) Windows XP-XP Home Edition & XP Professional (32 bit) Windows 7 (32 & 64 bit)

600 MHz Intel Pentium II or equivalent

Minimum 128MB RAM 100-200MB RAM used during installations and 100MB used after installation.

CD ROM Drive

Internet web application which provides the specified features in the familiar form of a web site accessible via the Internet Explorer web browser or Firefox web browser using the IE Tabs plug-in

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:

   Meter controlled, by time and date stamp

4. Specimen Sampling and Handling:

   Not Applicable

5. Calibration:

   Not Applicable

6. Quality Control:

   Not Applicable

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

For each meter that will be claimed as compatible with the ARK Care system a demonstration of accurate data transmission must be performed. This testing includes meter load up and meter memory rollover testing to confirm data synchronization upon after rollover.

Meters are loaded to memory capacity using the low and high controls, in addition a

mid level control solution was created by a technician using equal parts of the low and high control solutions. The assigned meter came with a data log sheet. Each result and its details were logged after each individual test. This methodology also prevented duplicate test results in the event that the same dose level was used successively and potentially skewing the data set. In addition the technicians varied the testing of control solutions, low, middle, and high to reduce potential misanalysis of duplicate results on the meter system.

After the meters were loaded to capacity they were passed off to the software validation group. Each meter system was then plugged into the ARK Care system, correct meter platform selected in ARK Care and then meter memory was uploaded and capacity verified against claim.

After initial memory capacity was confirmed ten more results were added to the meters. Results of the data additions were compared against the original load up data.

The above testing confirms the ARK Care system can accurately acquire blood glucose data from the tested glucose meter system.

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.