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

A. 510(k) Number:

k130657

B. Purpose for Submission:

New diabetes data management software accessory for use with GlucoDr Supersensor (k050985), GlucoDr Plus (k082328), and GlucoDr auto (k083628) blood glucose meters.

C. Manufacturer and Instrument Name:

All Medicus Co., Ltd.

LinkDr 2.0 Diabetes Management Software

D. Type of Test or Tests performed:

Diabetes data management system

E. System Descriptions:

1. Device Description:

The LinkDr 2.0 Diabetes Management Software is an optional accessory for use with compatible All Medicus brand blood glucose meters with data management capabilities. The subject device consists of a USB data transfer cable and software. The system allows the users 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.

2. Principles of Operation:

The LinkDr 2.0 Diabetes Management Software is an accessory to compatible All Medicus meters, which use specific test principles.

Operating System requirements for the LinkDr 2.0 Diabetes Management Software are as follows: Windows XP, Windows Vista or Windows 7, 32 bit. The system requirements are as follows: (1) Microsoft Windows personal computer, (2) video monitor and adapter with at least 800 x 600 pixels and 256 colors, (3) USB port, (4) CD-ROM drive, (5) Pentium 4 2.4 GHz processor, (6) 256 MB minimum of free RAM, and (7) 300~500 MB minimum of free hard disk space before installation, 100MB after installation.

The software provides the following features for the user:

- Transfers data from compatible All Medicus glucose meters to LinkDr 2.0 Diabetes Management Software via USB cable.
- Displays tables and charts for blood glucose data of registered members.
- Prompts registered members to login to access the software.
- Displays a preview page for printing the current page.
- Displays daily glucose readings in the Log book, meal block table and trend graph.
- Graphically displays the number of glucose values that fall above, below and within a specified target range.
- Displays the statistics report including trend chart and histogram.
- Calculates glucose averages and standard deviations in a statics table.
- Provides options to manage accounts of registered members.

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 the applicant's Hazard Analysis and software Documentation: Yes__X____ or No _____

F. Regulatory Information:

Device Name	Product Code	Classification	Regulation	Panel
Glucose Test System	NBW: Blood Glucose Test System, Over-the- Counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
Calculator/Data Processing Module for Clinical Use	JQP: Calculator/ Data Processing Module for Clinical Use	Class I	21 CFR § 862.2100	Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

   The LinkDr 2.0 Diabetes Management Software is a PC-based software intended for use in home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for effective diabetes management. It is intended for use as an accessory to compatible All Medicus brand blood glucose monitoring systems such as the GlucoDr Supersensor blood glucose meter, GlucoDr Plus blood glucose meter and GlucoDr auto blood glucose meter.

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

H. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:

   LifeScan IN TOUCH® Diabetes Management Software (k984527)

2. Comparison with Predicate Device:

Similarities and Differences		
Item	Candidate Device	Predicate Device
	LinkDr 2.0 Data Management Software	LifeScan IN TOUCH® Diabetes Management Software (k984527)

Intended Use	The LinkDr 2.0 Diabetes Management Software is a PC-based software intended for use in home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for effective diabetes management. It is intended for use as an accessory to compatible All Medicus brand blood glucose monitoring systems such as the GlucoDr Supersensor blood glucose meter, GlucoDr Plus blood glucose meter and GlucoDr auto blood glucose meter.	Same
Over-the-Counter	Yes	Same
Accessory to Glucose meter	Yes	Same
Intended user	Home Users/HCPs, single or multiple users	Same
Data Use	Data transferred from device cannot be changed or modified; manually entered data can be deleted or modified	Same
Setting target ranges	Yes	Same
Connectivity to Meter	USB Cable	Serial Cable
Manual Data Entry	Yes	Same
Logbook	Yes	Same

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

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

J. Performance Characteristics:

1. The performance characteristics listed below as applicable, are presented in the specific glucose clearances under k050985, k082328, and k083628.

- Analytical Performance:
  - *a) Accuracy:*
    See above statement under section J(1).

  - *b) Precision/Reproducibility:*
    See above statement under section J(1).

c) Linearity:
See above statement under section J(1).

d) Carryover:
See above statement under section J(1).

e) Interfering Substances:
See above statement under section J(1).

2. Other Supportive Instrument Performance Data Not Covered Above:

a) A usability study was performed with One hundred (100) lay and professional users with varying demographic characteristics (age, sex, and education level). The intent of the study was to verify software ease of use and label comprehension. Study participants also completed a questionnaire in response to whether the software, USB cable, and labeling are easy to use. The sponsor concluded that 100% of users were either somewhat satisfied or very satisfied with the software, USB cable, and user manual.

b) In an additional usability study with 20 lay users and 20 professional users, of various age, gender, educational background, and computer experience, software installation, connectivity and data transmission as intended to be used, was assessed and verified to achieve 100% accuracy for data transmission.

c) Bench Testing was performed on data from three meters for each meter type to test meter memory rollover and data transmission, this included full memory data transmission, plus additional data to validate correct data rollover in the app. All data fields were 100% accurate.

e) 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, architecture design chart, software design specification, traceability analysis, software development environment description, verification and validation testing, and revision level history. The sponsor reports that no unresolved anomalies are known to exist in the release version of the software.

f) The sponsor provided the results of a Flesch-Kincaid readability study which indicated a Grade Level Score of 7.3 for the LinkDr 2.0 Diabetes Management Software User Manual.

g) The sponsors provided the appropriate documentation certifying that electromagnetic testing (EMC) had been performed and the GP550 PC-Link Adaptor were found compliant (EN 61010-1, EN 61326-1).

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.