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

A. 510(k) Number:
k122142

B. Purpose for Submission:
New Device

C. Manufacture and Instrument Name:
Glooko, Inc.

Glooko Device System for Logbook Application & Glooko Logbook Charts

D. Type of Test or Test Performed:
Diabetes data management system

E. System Descriptions:

1. Device Description:

The Glooko device system includes two major modules: Glooko Logbooks™ and Glooko Logbook Charts™. The main function of Glooko Logbooks™ is to extract data from FDA-cleared glucose meters. The major function of Glooko Logbook Charts™ is to analyze and graph the data obtained from Glooko Logbooks™ to assist people with diabetes who self-manage their Blood Glucose (BG) readings**.**

The Glooko™ Logbooks
The Glooko™ Logbooks contain the following: Glooko MeterSync Cable, Glooko IR Adapter, and Glooko Logbook app. (1) The Glooko MeterSync Cable downloads data from compatible, FDA-cleared, commercial blood glucose meters into an iOS (iPhone Operating System) device by connecting the two components. One end of the Glooko MeterSync Cable plugs directly into the 30-pin connector slot of the iOS device. The 3.5mm end of the Glooko MeterSync Cable plugs directly into several FDA cleared, compatible meters to allow for the transfer of data. A listing of the FDA cleared meters, compatible with this system are identified in section H. Some meters require an additional 3.5mm to 2.5mm adapter to allow for this connectivity, while other meters transfer data through infrared, and thus require the use of the Glooko IR Adapter. The Glooko MeterSync Cable is designed to attach to a variety of compatible, FDA-cleared, commercial blood glucose meters. The users simply connect the supported meters to their iOS device and transfers the blood glucose meter data into the Glooko Logbook app. (2) The Glooko IR Adapter is designed to transmit data via infrared from a variety of compatible, FDA-cleared, commercial blood glucose meters into the Glooko Logbook app. The user connects the Glooko IR Adapter

to the 3.5mm adapter end of the Glooko MeterSync Cable to transmit data from the compatible meters. (3) The Glooko Logbook app performs the following functions: a) Syncs with compatible meters; b) Allows users to annotate glucose measurements with notes; c) Provides multiple view options for the data; and d) Shares the collected data in multiple formats to anyone the user selects. This iOS application logs the user's blood glucose values and meal tags that are downloaded from compatible blood glucose meters.

Glooko™ Logbook Charts

The Glooko™ Logbook Charts is a data management software tool designed to assist people with diabetes who self-manage their Blood Glucose (BG) readings. The Logbook Charts software is used in conjunction with the Glooko MeterSync Cable and Logbook Application. The MeterSync Cable and Logbook Application allow users to download BG readings from commercially available blood glucose meters to an iOS device. The Glooko Logbook Charts software tool enables the Glooko Logbook App users to chart and graph their BG values from the application. Glooko Logbook Charts is a spreadsheet program developed in Microsoft Excel and helps with quantitatively evaluating the BG data downloaded into the Glooko Logbook Application. Users can download the Glooko Logbook Charts sheet template from the Glooko website to generate and display reports on average BG values and BG trends. Several statistical parameters are calculated and the data is plotted as scatter grams relating blood glucose by time of day and by date. Glooko Logbook Charts specifically offers the following charts and table for view:
1) BG readings By Time of Day provides an overview of glucose readings during the day. 2) BG readings By Date: provides an overview of glucose readings over a specified date range. 3) BG readings Analysis By Time Of Day: provides an overview of analyzed glucose readings during the day with high and low values, percentiles, mean and medians, and BG readings Summary Statistics, which provides an overview of the analyzed glucose readings in table format.

2. Principles of Operation:

The Glooko™ system is a data management software tool.

Operating System requirements for the The Glooko device system are: Windows XP Professional, Windows server 2003, Windows Vista Professional or Windows 7 Professional. The system requirements are as follows: (1) Microsoft Windows personal computer, (2) CPU: 550 MHz Intel Pentium 3 or above, (3) DRAM: 512 or above, (4) HD: 2 GB or more, (5) Internet Explorer 7.0 or above, (6) USB 2.0 or above, (7) LCD screen with resolution of 1024x768 or above, (8) CD-ROM drive and (9) a printer (Optional).

iOS devices with versions employed to extract data from blood glucose (BG) meters.

iOS Device	Version
iPod touch	3rd Generation and above
iPhone	3GS, 4, 45
iPad	1, 2 and 3

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 __X__ or No____.

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 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)

* A premarket notification (510 (k)) is required for the Class I devices meeting the limitations under 21CFR 862.9 (c)(5) For use in diabetes management.

G. Intended Use:

1. Indication(s) for use:
   The Glooko device system for the Glooko Logbook Application and Glooko

Logbook Charts are data management software intended for use in home and professional settings to aid individuals with diabetes and their health care professionals in review, analysis and evaluation of blood glucose readings to support an effective diabetes management program. The Glooko device system for the Glooko Logbook Application connects to compatible FDA cleared meters and allows users to transfer their blood glucose meter results to their iPhone operating system platform.

The Glooko device system for the Glooko Logbook Application and Glooko Logbook Charts are not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

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

H. **Substantial Equivalence Information:**

	Glooko Logbook Charts / Logbook (K122142) **New Device**	**GlucoFacts Express Data Management Software (K082486)** **Predicate**
Intended use	• For use in home and professional settings • Device allows for the review, analysis and evaluation of BG results from a variety of FDA cleared meters	Same
Logbook for	Blood glucose readings, insulin and carbs intake	Same
Accessory to	Accu-Chek Aviva, Accu-Chek Compact Plus, Accu-Chek Nano, Bayer's Breeze 2, Bayer's Contour NEXT EZ, Bayer's Contour, Freestyle Freedom-Lite, Freestyle Lite, One Touch Ultra 2, OneTouch Ultra-Link and OneTouch Ultra-Mini, Glucocard 01, Glucocard Vital, ReliOn Confirm, ReliOn Prime meters.	Bayer's Contour, Contour TS, Breeze, and Breeze 2 blood glucose meters.
Use on	PC / Mac / iOS Platforms	PC
Data Analysis-Statistics	Mean, Median, Min, Max, Standard deviation, percentiles and Total	Mean, Min, Max, Standard deviation, Target (%), Above Target (%), Below

	Glooko Logbook Charts / Logbook (K122142) New Device	GlucoFacts Express Data Management Software (K082486) Predicate
Generated	number of tests	Target (%) and Total number of tests
Data Analysis-Ability to set target ranges	Yes	Same
Data Graphics-Reports, Charts, and Graphs	• Glucose by time of day • Glucose by date • Glucose analysis by time of day • Glucose summary statistics table	• Glucose trend results by day. • Daily blood glucose trends. • Weekly blood glucose trends. • Summary chart

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

- ISO 14971, Medical devices - Application of risk management to medical devices.
- AAMI TIR36:2007 Validation of software for regulated processes
- EN55D24: 2003 European standard for information technology equipment-immunity characteristics – limits and methods of measurement
- ANSIC63.42003: American national standard for methods of measurement of radio-noise emissions from low-voltage electrical and electronic equipment in the range of 9 khz to 40 Ghz
- EN55022:2006-A1:2007: Information Technology Equipment – Radio Disturbance Characteristics Limits and Methods of Measurements

J. Performance Characteristics:

1. Analytical Performance: The performance characteristics listed below as applicable, were established in the specific glucose meter clearance under k043474, k081389, k113137, k062347, k062058, k111268, k051839, k070850, k073416, k091102, k062195, k073231, k061118, k073416, and k091102.

   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:

1) The following documentation related to the software was reviewed and found to be acceptable: level of concern (moderate), software description, device hazard analysis, software requirements specifications, software design specification, revision level history, unresolved anomalies, software development environment description, verification testing and traceability analysis.

a. Glooko Logbook: The Glooko Logbook software was validated pursuant to the moderate level of concern requirements. Design validation testing confirmed that the Glooko device performs according to the stated intended use. Such testing included Characterization of the Glooko Logbook spreadsheet, Data Integrity Verification, Software Design Verification, Microsoft Excel Version Testing and Glooko Logbook Application Version testing. The validation of Glooko Device System for Logbook Application were validated in 29 patients with Type 1 and Type 2 diabetes and 2 healthcare professionals.

The test goals for this study were to validate:

- Accuracy of data download into the Glooko device System
- Ability to share (transmit, download, save and email) and annotate data
- Effectiveness of user manual
- Ease of use of the Glooko MeterSync Cable and the Logbook Application

b. Glooko Logbook Charts: A validation study was conducted based on pre-designed study protocol. The validation of Glooko Device System for Logbook Application & Glooko Logbook Charts were validated in 22 patients with Type 1 and Type 2 diabetes and 15 healthcare professionals. The test goals for this study were to validate:

- Effectiveness of the User Manual
- Ability to transmit, download, save and email csv files
- Ability to view and print the Logbook Chart graphs

2). A usability study was conducted using the Glooko Device System for Logbook Application in 20 patients with Type 1 and Type 2 diabetes. Additonal subsequent validation/human usability studies for Glooko device system in 9 diabetes patients and 2 healthcare providers.

a. The protocol and acceptant criteria of the usability studies were reviewed and found to be acceptable. The results from the usability study demonstrated that the product performs as intended in the hands of lay users and healthcare professionals. All test results fell within the pre-determined specification parameters.

b. A readability study was performed on the labeling and the above studies were reviewed and found to be acceptable.

3).The sponsor provided the appropriate documentation certifying that electromagnetic testing been evaluated.

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.