K132272

510(k) Summary (21 CFR § 807.92(c))

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter:	Glooko, Inc. 170A University Avenue Palo Alto, CA 94301
Contact:	Shilpa Mydur Director of Regulatory Affairs Phone: 650.720.5310 Email: shilpa@glooko.com
Date Summary Prepared:	16 October 2013
Device Trade Name:	Glooko Device System for Glooko Application
Common Name:	Blood Glucose Meter and Data Management System
Classification Name:	Glucose test system (21 CFR §862.1345) Calculator/data processing module for clinical use (21 CFR §862.2100)
Product Code:	NBW and JQP
Equivalent Device:	Glooko Device System for Glooko Logbook+ Application (K130886)

OCT 17 2013

Device Description:

Overview

The Glooko device system for Glooko Application is used to aid individuals with diabetes in the download, review, analysis, evaluation, and communication of their blood glucose readings. The system allows users to download readings from compatible, FDA-cleared, commercial blood glucose meters to their Android Operating System mobile devices, and then share this information with healthcare professionals. It is intended for use both in home and professional settings to support an effective diabetes management program. The data may be displayed on supported devices to provide an online view of all collected data and notes from the Glooko Android Application. The system does not provide treatment decisions and cannot be used as a substitute for professional healthcare advice.

The Glooko device system for Glooko Application consists of the following components

1. The **Glooko MeterSync Cable for Android**
2. The **Glooko Application**

Glooko MeterSync Cable

The Glooko MeterSync Cable downloads data from compatible, FDA-cleared, commercial blood glucose meters into an Android operating mobile device by connecting the two components. One end of the Glooko MeterSync Cable plugs directly into the 3.5 mm slot of the Android device. The 3.5mm end of the Glooko MeterSync Cable plugs directly into most compatible meters to allow for the transfer of data. 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 IR Adapter, which is integrated into the Glooko MeterSync Cable. The IR Adapter is designed to transmit data via infrared from a variety of compatible, FDA-cleared, commercial blood glucose meters that require infrared for data transfer.

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 Android mobile device and transfer the blood glucose meter data into the Glooko Android Application.

The Glooko Application:

The Glooko Application is one component of the Glooko data monitoring system used to aid individuals with diabetes in the review, analysis, evaluation, and communication of their blood glucose readings.

The Glooko Application collects and stores historical blood glucose data that has been downloaded from blood glucose meters. The Glooko Application also lets the user sync and view data from any supported compatible device when using the appropriate login information.

The Glooko Application keeps an organized log of the users blood glucose readings and allows for the addition of user-generated notes and meal tags. The Glooko Application also shows graphs, provides statistics, and allows for the sharing and viewing of blood glucose data across multiple supported devices running on Android.

The Glooko Application is compatible with the following FDA-cleared blood glucose meters:

- **Abbott:** FreeStyle Freedom Lite®, FreeStyle Lite®
- **Bayer:** Bayer's BREEZE®2, Bayer's CONTOUR®, Bayer's CONTOUR® NEXT EZ
- **LifeScan:** OneTouch® Ultra®2, OneTouch® UltraLink®, OneTouch® UltraMini®
- **Nipro:** Nipro TRUEbalance™ (K090495), Nipro TRUEread ™ (K042080), Nipro TRUEresult (K080641), Nipro TRUEtrack™(K040670)
- **Roche:** ACCU-CHEK® Aviva, ACCU-CHEK® Compact Plus, ACCU-CHEK® Nano
- **USB Meters:** Bayer's Contour USB (K091820), Bayer's Contour Next USB (K121087)

The Glooko Application can be operated on the following mobile devices, each supporting Android OS 2.3.3 and higher:

- HTC Desire HD (A9191), HTC Evo (PC36100), HTC Incredible S S710e
- LG Nexus 4, LG Optimus 2X (LG-P990)
- Motorola DROID X
- Samsung Ace (GT-S5830T), Samsung Galaxy Nexus, Samsung Galaxy Note (GT-N7000), Samsung Galaxy Note II (GT-N7100), Samsung Galaxy S+ (GT-I9001), Samsung Galaxy S II (GT-I9100), Samsung Galaxy S II (SGH-1757M), Samsung Galaxy S III (GT-I9300), Samsung Galaxy SIIII (GT-I9500)

The USB OTG Cable can be operated on the following Android devices, each supporting OS 3.1 and higher:

- Samsung Galaxy Nexus
- Samsung Note II (GT-N7100)
- Samsung Galaxy SII (SGH-1757M)
- Samsung Galaxy SIII (GT-I9300)
- Samsung Galaxy SIIII (GT-I9500)

The Glooko Application is compatible with the following web browsers:

- **Internet Explorer**- v8.0 and above
- **Firefox**- v3.0 and above
- **Chrome**- v14.0 and above
- **Safari**-v4.0 and above
- **iOS (Safari)**- v3.0 and above

Software Requirements:

The Glooko Application performs the following functions:

- **Sync** with compatible meters
- Allow users to **annotate** readings with notes
- Provide multiple **view** options for the data
- **Share** the collected data
- **Transmit** and **view** readings, graphs, statistics and notes across supported multiple devices and web browsers when using consistent authentication credentials (username and password)
- Ability to connect to USB supported blood glucose meters using an off the shelf micro USB cable

Technological Characteristics:
The table below provides the comparison of technological characteristics between the subject and predicate device

Table 1: Summary of Technological Characteristics

Product	Glooko Device System for Glooko Logbook+ Application K130886 (Predicate Device)	Glooko Device System for Glooko Application K132272 (Subject Device)
Indications for Use	The Glooko device system for Glooko Application is 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 Glooko Application connects to compatible FDA cleared meters and allows users to transfer their blood glucose meter results to their mobile devices. The Glooko device system for Glooko Application is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.	Same
Software	Glooko Logbook+ Application (iOS platform)	Glooko Application (Android operating system platform)
Hardware	MeterSync Cable IR Adapter	MeterSync Cable with integrated IR Adapter

Product	Glooko Device System for Glooko Logbook+ Application K130886 (Predicate Device)	Glooko Device System for Glooko Application K132272 (Subject Device)
Blood glucose meter compatibility	Abbott: FreeStyle Freedom Lite®, FreeStyle Lite® Bayer: Bayer's BREEZE®2, Bayer's CONTOUR®, Bayer's CONTOUR® NEXT EZ. LifeScan: OneTouch® Ultra®2, OneTouch® UltraLink®, OneTouch® UltraMini® Roche: ACCU-CHEK® Aviva, ACCU-CHEK® Compact Plus, ACCU-CHEK® Nano	Abbott: FreeStyle Freedom Lite®, FreeStyle Lite® Bayer: Bayer's BREEZE® 2, Bayer's CONTOUR®, Bayer's CONTOUR® NEXT EZ, Bayer's LifeScan:OneTouch® Ultra®2, OneTouch® UltraLink®, and OneTouch® UltraMini® Roche: ACCU-CHEK® Aviva, ACCU-CHEK® Compact Plus, ACCU-CHEK® Nano
Meters not supported by the predicate device but supported by current device		Nipro TRUEbalance™ (K090495), Nipro TRUEread ™ (K042080), Nipro TRUEresult (K080641), Nipro TRUEtrack™(K040670) Bayer's Contour USB (K091820) Bayer's Contour Next USB (K121087)
Meters supported by the predicate device but not by the current device	GLUCOCARD: GLUCOCARD® 01, GLUCOCARD® VitalTM ReliOn: ReliOn® Confirm, ReliOn® Prime iSENS: CareSens N and CareSens N POP	
Operating System	iOS 5.0 and higher	Android OS 2.3.3 or higher

Product	Glooko Device System for Glooko Logbook+ Application K130886 (Predicate Device)	Glooko Device System for Glooko Application K132272 (Subject Device)
Hardware	• iPod touch®: 3rd and 4th generations • iPhone®: 3GS, 4, 4S • iPad®: iPad 1, iPad 2, and iPad (3rd generation) –(Accessed in 2x mode) • iPod touch 5th generation, iPhone 5, iPad mini, and iPad 4th generation (These devices require Apple's off-the-shelf Lightning to 30-pin adapter for connection.)*	• HTC Desire HD (A9191), HTC Evo (PC36100), HTC Incredible S S710e • LG Nexus 4, LG Optimus 2X (LG-P990) • Motorola DROID X • Samsung Ace (GT-S5830T), Samsung Galaxy Nexus, Samsung Galaxy Note (GT-N7000), Samsung Galaxy Note II (GT-N7100), Samsung Galaxy S+ (GT-I9001), Samsung Galaxy S II (GT-I9100), Samsung Galaxy S II (SGH-1757M), Samsung Galaxy S III (GT-I9300), Samsung Galaxy SIIII (GT-I9500)
Syncs with compatible meters	Yes	Yes
Allow users to annotate readings with notes	Yes	Yes
Provide multiple view options for the data	Yes	Yes
Share the collected data	Yes	Yes
Provide statistics	Yes, across multiple devices and supported web browsers.	Yes, across multiple devices and supported web browsers.
Graph the glucose readings	Yes, across multiple devices and supported web browsers.	Yes, across supported web browsers.
Allow goals to be set	Yes	No
Transmit and view data across supported multiple devices and web browsers using consistent authentication credentials (username/password)	Yes	Yes

Intended Use:

The Glooko device system for Glooko Application is data management software intended for use in home and professional settings to aid individuals with diabetes and their healthcare professionals in review, analysis and evaluation of blood glucose readings to support an effective diabetes management program. The Glooko device system for Glooko Application connects to compatible FDA cleared meters and allows users to transfer their blood glucose meter results to their mobile devices running on Android operating system.

The Glooko device system for Glooko Application is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Summary of Testing:

The Glooko Application underwent verification and validation testing. A brief summary of the tests performed is described below. These studies demonstrated that the Glooko Device System for Glooko Application performed according to the specifications and the intended use.

Software Verification and Validation

- The Glooko Device system (Glooko Application, and Cable) 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. Device evaluation consisted of functional testing performed pursuant to Glooko's design verification protocol, which referenced FDA's guidance document for medical devices containing software. Such testing included Data Integrity Verification, Software Design/features Verification, and error handling testing. All test results fell within the pre-determined specification parameters.

Statement of Equivalence:

The Glooko Device System for Glooko Application is substantially equivalent to the predicate device with regards to its intended use and function. Both the subject and predicate devices use the exact same technology to download data from compatible FDA cleared blood glucose meters. Both the subject and predicate device are able to analyze blood glucose meter data producing basic statistics and graphs.

Summary:

Based on the information provided in this premarket notification, the Glooko device system for Glooko Application is substantially equivalent to the predicate device and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 17, 2013

Glooko, Inc.
c/o Shilpa Mydur
170A University Avenue
PALO ALTO CA 94301

Re: K132272
Trade/Device Name: Glooko Device System for Glooko Application
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: September 16, 2013
Received: September 17, 2013

Dear Shilpa Mydur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol E. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

glooko

K133272

510(k) Number if Known: N/A

Device Name: Glooko Device System for Glooko Application

Indications for Use:
The Glooko device system for Glooko Application is 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 Glooko Application connects to compatible FDA cleared meters and allows users to transfer their blood glucose meter results to their mobile devices running on Android Operating System.

The Glooko device system for Glooko Application is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Prescription Use ____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Stayce F Beck

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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