February 2, 2018

Glooko, Inc.
Tejasvi Pasi
Senior Regulatory Manager
899 West Evelyn Avenue
Mountain View, California 94041

Re: K171450
Trade/Device Name: Glooko Mobile Insulin Dosing System (MIDS)
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: December 29, 2017
Received: January 2, 2018

Dear Tejasvi Pasi:

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 Part 801); 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171450

Device Name
Glooko Mobile Insulin Dosing System (MIDS)

Indications for Use *(Describe)*
The Glooko Mobile Insulin Dosing System (MIDS) is indicated for the management of type 2 diabetes by calculating appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a physician or healthcare provider knowledgeable in the care and management of diabetes. The physician or healthcare provider must activate the MIDS dose calculator and configure the patient-specific parameters. The system is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary for K171450

5.1 Submitter Information

Name:	Glooko Inc.
Address:	303 Bryant Street, Mountain View, CA 94041, USA
Phone:	(650) 720-5310
Fax:	(650)-720-5310
Contact Name:	Tejasvi Pasi
Date of Summary:	02/01/2018

5.2 Subject Device

Trade Name:	Glooko Mobile Insulin Dosing System (MIDS)
Common Name:	Diabetes Management Software
Classification Name:	Calculator, Drug Dose
Regulation Number:	21 CFR 868.1890
Regulation Name:	Predictive pulmonary – function value calculator
Regulatory Class:	Class II
Product code:	NDC
Classification Panel:	General Hospital

5.3 Predicate Device

Trade Name: (K161433)	Insulia Diabetes Management Companion
Common Name:	Diabetes Management Software
Classification Name:	Calculator, Drug Dose
Regulation Number:	21 CFR 868.1890
Regulation Name:	Predictive pulmonary – function value calculator
Regulatory Class:	Class II
Product code:	NDC
Classification Panel:	General Hospital

5.4 Reference Device

Trade Name: (K132272)	Glooko Device System for Glooko Application
Common Name:	Blood Glucose Meter and Data Management System

Classification Name:	Glucose Test System, Calculator Data Processing Module for Clinical Use
Regulation Number:	21 CFR 862.1345 21 CFR 862.2100
Regulatory Class:	Class II, Class I
Product code:	NBW, JQP
Classification Panel:	Clinical Chemistry

5.5 Device Description

The Glooko MIDS system will be an optional new module to support the titration of long acting basal insulin doses. Health care providers (HCPs) will be able to opt-in to this new MIDS module and use it with a subset of their patients. Although the Glooko App may interact with Blood Glucose (BG) meters, insulin pumps and Continuous Glucose Meters (CGM), the MIDS interface will get data **ONLY** from the BG meters

Glooko MIDS consists of the following two interfaces:

- MIDS Provider Interface on the Glooko Web Application for use by HCP's to prescribe long acting insulin doses for their patients
- MIDS Patient interface on the Glooko mobile application for use by patients on compatible iOS and Android phones

Glooko MIDS provides directions to the patient based on a pre-planned treatment program as suggested by their HCP for titrating long acting insulin doses. Glooko MIDS is for titrating long acting insulin doses only.

5.6 Indications for Use

The Glooko Mobile Insulin Dosing System (MIDS) is indicated for the management of type 2 diabetes by calculating appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a physician or healthcare provider knowledgeable in the care and management of diabetes. The physician or healthcare provider must activate the MIDS dose calculator and configure the patient-specific parameters. The system is not

intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

5.7 Comparison to Predicate Device

Feature	Glooko Mobile Insulin Dosing System (Subject device)	Insulia Diabetes Management Companion (Predicate device)
Code	NDC	NDC
Class	II	II
Regulation Name/Regulation	Predictive pulmonary-function value calculator/21 CFR 868.1890	Predictive pulmonary-function value calculator/21 CFR 868.1890
K Number	K171450	K161433
Indications for Use*	The Glooko Mobile Insulin Dosing System (MIDS) is indicated for the management of type 2 diabetes by calculating appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a physician or healthcare provider knowledgeable in the care and management of diabetes. The physician or healthcare provider must activate the MIDS dose calculator and configure the patient-specific parameters. The system is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.	Insulia Diabetes Management Companion is indicated for use by healthcare professionals (HCPs) and their type 2 adult diabetes patients treated with long-acting insulin analog. Insulia Diabetes Management Companion is intended to provide secure capture, storage and transmission of diabetes-related healthcare information, to enhance data management, to display reports and graphs, and to aid the HCP and the patient in the review, analysis, and evaluation of patient data in order to support effective diabetes management. Insulia Diabetes Management Companion includes a basal calculator intended to provide direction to the patient in response to blood glucose and health events, within the scope of a pre-planned treatment program from a healthcare professional for insulin adjustments, similar to the directions provided to patients as a part of routine clinical practice. Insulia Diabetes Management Companion includes software intended for use on commercially available

Feature	Glooko Mobile Insulin Dosing System (Subject device)	Insulia Diabetes Management Companion (Predicate device)
		mobile platforms, personal computers, in the home or in professional healthcare settings, and uses generally available networks and communication protocols. Insulia Diabetes Management Companion is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.
Components	Patient mobile based application, patient and HCP web based application	Software only, patient mobile based application, patient and HCP web based application
Treatment Guidance	Adjustments to insulin doses within the scope of a pre-planned, physician specified treatment program similar to routine clinical practice	Adjustments to insulin doses within the scope of a pre-planned, physician specified treatment program similar to routine clinical practice
Type of Calculated Insulin	Basal Insulin	Basal Insulin
Manual BG Entry	No	Yes
Logbook	Yes	Yes
Reports & Statistics	Yes	Yes
Coaching Messages	No	Yes
Secure Database	Yes	Yes
Data Transfer	Internet	Internet

*Glooko MIDS has the same intended use as the predicate device. Both software applications are intended for use by healthcare professionals and their patients with type 2 diabetes for calculating appropriate long-acting insulin doses. Glooko MIDS and the predicate device provide HCP-configured directions within the scope of a pre-planned treatment program for titrating long-acting insulin as a part of routine clinical practice. The proposed indications for use for the subject device are similar to and consistent with that of the predicate device, and do not raise different questions of safety or effectiveness.

5.8 Comparison to Reference Device

The reference device supports the BG entry method for the subject device. Both the subject and the reference device do not support manual entry of BG data. In both the Glooko MIDS and the reference device BG data is transferred from supported BG meters to the Glooko Application via cable(s) or Bluetooth enabled BG meters.

Feature	Glooko Mobile Insulin Dosing System (Subject device)	Glooko Device System for Glooko Application (Reference device)
K Number	K171450	K132272
BG Entry	BG data is transferred from the BG meter to the Glooko Application via cable(s) or Bluetooth enabled BG meters	BG data is transferred from the BG meter to the Glooko Application via cable(s) or Bluetooth enabled BG meters

5.9 Performance Data Demonstrating Substantial Equivalence

The Glooko MIDS underwent Human Factors validation testing and software performance testing to support a determination of substantial equivalence.

The Glooko MIDS software was validated pursuant to the Major Level of Concern requirements. Design validation testing and human factors study results confirmed that the Glooko MIDS software performs according to the stated intended use. The Human Factors validation was documented according to FDA Guidance - Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016). Software evaluation consisted of functional testing performed pursuant to Glooko's design verification protocol. All of the software tests were documented according to FDA's guidance document - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). All test results fell within the pre-determined specification parameters and acceptance criteria.

5.10 Statement of Equivalence

The Glooko MIDS is substantially equivalent to the predicate device with regards to its intended use and function.

5.11 Conclusion

Glooko MIDS has similar indications for use and similar technological characteristics as those of the predicate device Insulia Diabetes Management Companion. Performance testing of the Glooko MIDS software has demonstrated that Glooko MIDS performs as intended and is substantially equivalent to the predicate device. Based on the product technical information, intended use, human factors and validation data provided in this pre-market notification, the Glooko MIDS software has been shown to be substantially equivalent to the currently marketed predicate device.