June 14, 2018

Intuity Medical, Inc.
% Cindy Domecus
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, CA 94010

Re: K181316
Trade/Device Name: POGO Automatic Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: May 17, 2018
Received: May 18, 2018

Dear Cindy Domecus:

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 and Part 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.

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 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,

Kellie B. Kelm -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

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)*
k181316

Device Name
POGO Automatic Blood Glucose Monitoring System

Indications for Use *(Describe)*
The POGO Automatic Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The POGO Automatic Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The POGO Automatic Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The POGO Automatic Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. The POGO Automatic Blood Glucose Monitoring System is indicated for use in adults and adolescents (13 and up).

POGO Automatic Test Cartridges are for use with the POGO Automatic Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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.

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510(k) Summary, k181316

510(k) Owner

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Date Summary Prepared

June 11, 2018

Device Name and Classification

Trade Name	POGO® Automatic™ Blood Glucose Monitoring System
Common Name	Glucose Test System
Classification	Class II
Regulations	21 CFR 862.1345
Product Codes	NBW
Panel	Clinical Chemistry

Predicate Device

The predicate device for the POGO Automatic Blood Glucose Monitoring System (POGO BGMS) is the earlier version of the system cleared under k162203 on April 6, 2017.

Device Description

The POGO BGMS is a quantitative assay for the detection of glucose in capillary whole blood sampled from the fingertip. The system includes multiple glucose-oxidase-based dry-reagent test strips housed in a cartridge and a photometer to read the glucose-dependent color change from the in-use strip. The meter uses calibration information from a barcode on the disposable cartridge to convert the reflectance information into a plasma-equivalent glucose value. A Bluetooth Low Energy (BLE) module in the meter allows the user to authorize the POGO meter to send data wirelessly, securely, and automatically after each test to specified electronic computing devices.

The POGO BGMS automates finger lancing, blood sample collection and placement onto the test strip, and calculation of the blood glucose result, and so requires significantly fewer steps than existing BGMSs to obtain a glucose result. The POGO BGMS accomplishes this via a 10-test cartridge where each foil-sealed test includes a hollow lancet, spring, and test strip. The user does not need a separate lancing device since the lancing mechanism is built into individual test cells of the cartridge. The blood sample is drawn into the test through capillary action and the meter, by monitoring the time and degree of blood spreading on the reagent pad, can detect when the test is under-filled and allow the user a limited amount of time to add blood to the test trip to obtain a glucose result rather than an error. Additionally, used tests are retained within the cartridge for added user convenience.

Indications for Use

The POGO Automatic Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The POGO Automatic Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The POGO Automatic Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The POGO Automatic Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. The POGO Automatic Blood Glucose Monitoring System is indicated for use in adults and adolescents (13 and up).

POGO Automatic Test Cartridges are for use with the POGO Automatic Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Comparison to Predicate Device -- POGO BGMS

Characteristic	POGO BGMS Subject Device	POGO BGMS k162203 Predicate Device
Intended Use	Quantitative measurement of blood glucose	Same
Indications For Use	The POGO Automatic Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The POGO Automatic Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The POGO Automatic Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The POGO Automatic Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. The POGO Automatic Blood Glucose Monitoring System is indicated for use in adults and adolescents (13 and up). POGO Automatic Test Cartridges are for use with the POGO Automatic Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.	Same
Rx/OTC	OTC	Same
Classification Regulation	862.1345	Same
Product Codes	NBW	Same
Product Design	Battery-powered handheld meter	Same
Delivery of Blood to Reagent Pad via Capillary Action	Yes	Same
Automatic Blood Sample Collection	Yes	Same
Detects Under-filled Reagent Pad	Yes	Same

Characteristic	POGO BGMS Subject Device	POGO BGMS k162203 Predicate Device
Allows Blood Reapplication to Complete Test	Yes, provides glucose result or error code after blood addition to under-filled strip	Same
Time period allowed for patient to add more blood when reagent pad is under-filled	15 seconds	Same
Time period allowed for patient to apply blood when blood does not reach reagent pad	90 seconds	Same
Meter enforces limits on strip exposure?	Yes, device design prevents strip use after 5 minute exposure (open cell time window)	Same
Patient able to re-use lancet?	No, device design prevents re-use	Same
Cal Coding	Automated	Same
Detection Method	Photometric (LED)	Same
Enzyme	Glucose oxidase	Same
Hematocrit Range	20% to 60%	Same
Humidity Range	10% to 90% RH	Same
Lancing Device	Integrated in Meter with Strip/Lancet in Cartridge	Same
Measurement Range	20 - 500 mg/dL	Same
Minimum Sample Size	0.25 µL	Same
Monitor Memory	500 results	Same
Operating Temperature Range	50 to 104º F	Same
Principle of Operation	Glucose is oxidized by the enzyme glucose oxidase and electrons are transferred to form the intermediate hydrogen peroxide. Horseradish peroxidase catalyzes the transfer of electrons between hydrogen peroxide and precursor dye molecules to form a blue oxidation product, the concentration of which is proportional to the concentration of glucose in the sample. The amount of color formed is read by a photometer in the meter.	Same

The subject modifications for the POGO BGMS do not affect any of the above attributes that were included in the substantial equivalence section of the predicate device and relied upon for the substantial equivalence finding for the predicate device, k162203. Similarities between the between the subject and predicate POGO BGMS include:

- Same fundamental technological characteristics. The following remain unchanged: blood sampling and blood glucose measurement, use of the same cartridge (which contains the reagent system used to measure blood glucose), technology and procedure to acquire a blood sample and monitor the color development on the reagent pad and the algorithm to calculate a glucose value from the reaction at the reagent pad
- Same intended use and indications for use

Differences between the subject and predicate POGO BGMS include:

- the addition of BLE capability,
- a pixelated versus a segmented display screen,
- a new hard coat material on the display lens,
- addition of graphical elements, settings, and alerts to the display,
- a speaker versus a piezo annunciator, and
- a replacement of rubber feet on the bottom of the device for one large slip-resistant label.

The modifications do not alter fundamental technologies or principles of operation of the POGO BGMS.

Summary of Nonclinical Performance Data

Multiple nonclinical tests were identified via risk assessment activities as requirements to demonstrate comparable safety and effectiveness between the predicate and subject devices. The subject device achieved a "Pass" result for all of those tests, namely:

1. Performance tests conducted to demonstrate that items modified or replaced from the predicate device met the performance specifications established for those components;
2. Mechanical, Environmental, and Electrical safety tests appropriate for SMBG devices;
3. Cleaning and Disinfection efficacy and robustness challenges on raw materials and the assembled device;
4. Software V&V;
5. Bluetooth wireless proximity and coexistence testing; and
6. Labeling readability.

Conclusion

Results from the nonclinical testing using the modified POGO BGMS demonstrate that it is substantially equivalent to the predicate device. The modifications to the POGO BGMS do not raise different questions of safety and effectiveness and the testing performed to evaluate the modifications confirms that the modified device is as safe and effective and is substantially equivalent to the predicate device.