



Food and Drug Administration
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INTUITY MEDICAL, INC
c/o CINDY DOMECUS
DOMECUS CONSULTING SERVICES, LLC
1171 BARROILHET AVENUE
HILLSBOROUGH CA 94010

April 25, 2016

Re: K152493

Trade/Device Name: Pogo Automatic Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: August 31, 2015
Received: September 2, 2015

Dear Ms. 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 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 Industry and Consumer Education 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” (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,


Katherine Serrano -S

For: Courtney 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

Indications for Use

510(k) Number (if known)
k152493

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.

POGO Control Solutions are used with the POGO Automatic Meter to indicate appropriate user technique and to indicate that the POGO Automatic Test Cartridge and POGO Automatic Meter are functioning properly.

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

1 510(k) Owner

Owner: Intuity Medical, Inc.
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2 Submission Correspondent:

Cindy Domecus, R.A.C. (US & EU)
 Principal, Domecus Consulting Services LLC
 (650) 343-4813

3 Date Summary Prepared: April 20, 2016

4 Device name - trade name and common name, and classification

Trade Name	POGO® Automatic™ Blood Glucose Monitoring System	POGO® Control Solution
Common Name	Glucose Test System	Quality control material (assayed and unassayed)
Classification	Class II	Class I
Regulations	21 CFR 862.1345	21 CFR 862.1660
Product Codes	NBW, CGA	JJX
Panel	Clinical Chemistry	Clinical Chemistry

5 Identification of the legally marketed predicate device

The POGO® Automatic™ Blood Glucose Monitoring System (POGO BGMS) is substantially equivalent to the Accu-Chek Compact Plus Blood Glucose Monitoring System (Roche Diagnostics, Inc., Indianapolis, IN), cleared under k081389 on July 15, 2008.

The POGO Control Solutions are substantially equivalent to Glucose Meter-Check® Solution Roche Accu-Chek (Bionostics, Inc., Devens, MA), cleared under k123851 on February 14, 2013.

6 Device Description

The POGO Automatic Blood Glucose Monitoring System (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.

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. Additionally, used tests are retained within the cartridge for added user convenience. Control solutions are available to confirm correct system performance.

7 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.

POGO Control Solutions are used with the POGO Automatic Meter to indicate appropriate user technique and to indicate that the POGO Automatic Test Cartridge and POGO Automatic Meter are functioning properly.

8 Technological Characteristics Comparison

POGO BGMS

CHARACTERISTIC	POGO BGMS	Accu-Chek Compact Plus k081389
Intended Use	Quantitative measurement of blood glucose	Same
Indications For Use	<p>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.</p> <p>The POGO Automatic Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.</p> <p>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).</p> <p>POGO Automatic Test Cartridges are for use with the POGO Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.</p> <p>POGO Control Solutions are used with the POGO Blood Glucose Meter to indicate appropriate user technique and to indicate that the test cartridge and meter are functioning properly.</p>	<p>The Accu-Chek Compact Test Drums are used with the Accu-Chek Compact or Compact Plus Meter. The Accu-Chek Compact and Compact Plus System is designed to quantitatively measure the concentration of glucose in capillary and venous whole blood. The device is indicated for professional use and over-the-counter sale. The Accu-Chek Compact and Compact Plus System are indicated for lay person use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf, and palm.</p>
Rx/OTC	OTC	Same
Classification Regulation	862.1345	Same
Product Codes	NBW, CGA	NBW, LFR
Product Design	Battery-powered handheld meter	Same
Automatic Blood Sample Collection	YES	NO
Cal Coding	Automated	Same

CHARACTERISTIC	POGO BGMS	Accu-Chek Compact Plus k081389
Detection Method	Photometric (LED)	Same
Enzyme	Glucose oxidase	Glucose dehydrogenase
Hematocrit Range	20% to 60%	25% to 65%
Humidity Range	10 – 90% RH	15% - 85% RH
Lancing Device	Integrated in Meter with Strip/Lancet in Cartridge	Detachable from Meter
Measurement Range	20-500 mg/dL	10-600 mg/dL
Minimum Sample Size	0.25 µL	0.6 µL
Monitor Memory	500 results	Same
Operating Temperature Range	50 to 104° F	Same
Power Source	2 AAA batteries	Same
Test Strip Configuration	10 Test Cartridge	17 Test Strip Drum
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.	Glucose is oxidized by the enzyme PQQ-dependent glucose dehydrogenase and electrons are transferred to form a reduced mediator intermediate. The reduced mediator transfers electrons to a dye molecule, which turns blue when reduced, 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.

Comparison of Indications for Use

POGO BGMS and the listed predicate device have the same intended use; namely, the quantitative measurement of blood glucose. The proposed indications for use are narrower than those of the predicate device, since only indicated for fingerstick testing and only by a single person in the home setting. Fingerstick testing is the most often recommended site for blood glucose monitoring devices. Single person use only provides additional protection against blood borne pathogen transmission.

Comparison of Technological Characteristics

The technology used in the POGO BGMS is similar to that used in the predicate device. Similar elements include: a motor-driven multi-strip drum with a barcode containing expiration and calibration information, a means to lance the subject, a capillary channel to automate blood delivery from the fingerstick wound to the reagent section of the test strip, and an optical system to read color developed on the test strip. The test strips are

all dry-reagent chemistries specific for glucose in samples of whole blood delivered via capillary action.

Differences between the POGO BGMS and the predicate device include: a different enzyme in the test strip (glucose oxidase in POGO BGMS and glucose dehydrogenase in the predicate), a new, sterile, single-use and auto-disabling lancet is provided with every test in the POGO BGMS versus user-controlled lancet replacement or re-use in the predicate, smaller minimum sample volume in POGO BGMS (0.25 µL versus 0.6 µL in the predicate), a different number of strips in the cartridge (10 in POGO BGMS vs 17 in predicate), and an automatic storage of used test strips and lancets within the cartridge for POGO BGMS versus user-required disposal of at least the test strip after every test in the predicate.

POGO Control Solutions

CHARACTERISTIC	POGO Control Solutions	Glucose Meter-Check Solution Roche Accu-Chek k123851
Intended Use	To test performance of blood glucose test system	Same
Indications for Use	POGO Control Solutions are used with the POGO Blood Glucose Meter to indicate appropriate user technique and to indicate that the test cartridge and meter are functioning properly POGO Control Solution should be used for patient training and educational purposes	Glucose Meter-Check Solution Roche Accu-Chek is intended to assess the performance of the following Roche Accu-Chek blood glucose monitoring systems: Roche Accu-Chek Aviva and Accu-Chek Aviva Combo using Aviva Plus test strips Roche Accu-Chek Active using Accu-Chek Active test strips Roche Accu-Chek Compact Plus using Accu-Chek Compact test strips Roche Accu-Chek Advantage using Comfort Curve test strips
Classification Regulation	862.1660	Same
Product Codes	JJX	Same
Value Assignment	Determined by analysis of glucose in control solution on commercial lots of test strips	Determined by analysis of glucose on commercial lots of test strips qualified for proper measurement using manufacturer recommended control solution
Target Range	Level 1 midpoint target is 150 mg/dL Level 2 midpoint target is 75 mg/dL	Midpoint values assignment of 108 to 147 mg/dL depending on meter type
Auto Dose Test Strip	Yes	No
Auto QC Detection	Yes	Yes, for some meter types

CHARACTERISTIC	POGO Control Solutions	Glucose Meter-Check Solution Roche Accu-Chek k123851
Auto Pass/Fail Detection	Yes	No
Matrix	Water, buffers, salts, viscosity modifier, glucose, preservatives, dyes	Same
Container	Individual, single use 25 uL HDPE wand inside foil pouch Level 1 wand is blue HDPE Level 2 wand is red HDPE	6 mL white LDPE
Analyte	Glucose, purified chemical source	Same
Color	Red	Same

Comparison to Predicate

POGO Control Solutions are intended to indicate whether the meter and cartridge are performing correctly. The solution is supplied in a single-use plastic wand that is foil packaged. There are two levels of control solution available and are easily distinguishable by the color of the wand—Level 1 control solution is a blue wand, and Level 2 control solution is a red wand. The solution itself is similar to the predicate device in multiple ways—it is a buffered, aqueous, viscosity-modified solution containing a known quantity of glucose. The way in which the response range is determined is similar to the predicate; the solution is tested on each cartridge lot, and an allowed range of $\pm 15\%$ is placed around the mean calculated glucose response. The fact that the sample being run on the BGMS is control solution is automatically detected by the BGMS and reported to the user in both the predicate and POGO systems.

The POGO control solution differs from the predicate in the following ways:

- The control solution wand is a single-use disposable applicator containing less than 50 uL of solution and allows the user to complete a control solution test via the automated lancing and sample transport features of the POGO BGMS. The user follows the same steps as for a blood test, but presses the control solution wand on the meter test port instead of their finger.
- The POGO BGMS is designed to automatically distinguish Level 1 from Level 2 control and automatically report a “P”ass or “F”ail result on the display by evaluating whether the result of the control solution test is within 15% of the value encoded on the cartridge barcode for each level of control solution.

9 **Brief Discussion of Nonclinical Data**

A series of analytical studies were performed with the POGO BGMS to support substantial equivalence, and the summarized performance data were as follows:

Repeatability with Whole Blood:

Five whole blood samples ranging from 41.8 mg/dL to 306.7 mg/dL were tested in replicates of 10 with 10 meters. The %CVs ranged from 2.3% to 3.4%. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides repeatable results.

Intermediate Precision with Commercial Controls:

Three levels of commercial controls (approximately 30, 100, and 300 mg/dL) were tested in duplicate with 10 meters over 10 days. The %CVs were 6.5% (2.1 SD), 3.1%, and 3.2% for the three levels, respectively. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides precise results.

Linearity:

One whole blood sample was spiked with nine levels of glucose ranging from 17 mg/dL to 529 mg/dL; the samples were tested in replicates of 10. The protocol acceptance criteria were met, demonstrating that the POGO BGMS is linear throughout the claimed dynamic range.

Hematocrit Tolerance:

Studies were done with four levels of glucose (60, 120, 250, and 400 mg/dL) and seven different hematocrits ranging from 20% to 60%. The protocol acceptance criteria were met, demonstrating that the POGO BGMS is accurate throughout the claimed 20-60% hematocrit range.

Altitude Tolerance:

Studies were performed at sea level, 5,000 feet, and 10,000 feet altitude with blood at nominal glucose levels of 60, 120, and 300 mg/dL. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides accurate results at altitudes up to the claimed 10,000 feet.

Temperature Tolerance:

Temperature testing was performed at five temperatures from 4°C to 40°C and at nominal glucose levels of 60, 120, and 300 mg/dL. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides accurate results across both the tested 4°C to 40°C range and the claimed temperature range of 10°C to 40°C.

Humidity Tolerance:

Humidity testing was performed at 10%, 50%, and 90% relative humidity (RH) and nominal glucose levels of 60, 120, and 300 mg/dL. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides accurate results when tested across the claimed humidity range of 10% to 90% RH.

Combinations of Temperature and Humidity Tolerance:

Testing was performed at nominal conditions of 25°C and 45% relative humidity (RH), and at four extreme conditions of 10°C and 40°C crossed with 10% and 90% RH. Three nominal glucose levels of 60, 120, and 300 mg/dL were used. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides accurate results at extreme combinations of temperature and humidity.

Sample Volume Tolerance:

Studies were done to confirm the accuracy of the POGO BGMS across a range of whole blood volumes, from less than the claimed minimum amount (minimum claim 250 nL) to volumes beyond what can be achieved in normal device usage, and at nominal glucose levels of 60, 120, and 300 mg/dL. The system was accurate when tested with a sample volume between 250 and 1000 nL. At sample volumes of less than the 250 nL claimed minimum volume, the POGO BGMS provided either no result, or an accurate glucose result. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides accurate results across a wide range of sample volumes.

Interfering Substances:

The POGO BGMS was challenged at two glucose concentrations (approximately 80 mg/dL and 320 mg/dL) with both therapeutic and toxic levels of multiple potentially interfering substances, including bilirubin, cholesterol, hemoglobin, triglycerides, uric acid, multiple common medications, and alternate sugars. No interference beyond the acceptance criteria was noted. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides accurate results when the sample contains up to the tested concentrations of potentially interfering substances.

Test Range Limits:

The behavior of the POGO BGMS at the high and low limits of quantitation were challenged with blood spiked to levels of 10, 550, and 1100 mg/dL. The meter displayed “LO” for all tested glucose levels below 20 mg/dL and “HI” for all tested glucose levels above 500 mg/dL. No numeric glucose results were displayed. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides correct responses with blood samples outside of the claimed quantitation range of the system.

Open Test Tolerance:

Testing was performed to verify the length of time a test can be open prior to use and still meet system accuracy requirements. Nominal blood glucose levels of 80 and 320 mg/dL were tested. The protocol acceptance criteria were met for the 6.5 minute time point, demonstrating that the POGO BGMS provides accurate results at up to the claimed 5 minutes of open time prior to the start of a test.

Open Cartridge Tolerance:

Testing was performed to support the entire open cartridge stability claim in terms of time, temperature (4°C-30°C) and humidity (10-90%). Cartridges were tested after up

45 days of exposure in the environmental chamber using venous whole blood spiked to nominal glucose levels of 80 mg/dL and 320 mg/dL. The protocol acceptance criteria were met, demonstrating that the POGO BGMS provides accurate results for the claimed open cartridge duration of 45 days.

10 Brief Description of Clinical Data

A total of 287 subjects with diabetes were enrolled across US clinical sites; the subjects represented a wide range of demographic factors. Subjects were asked to read the product labeling, perform a POGO BGMS test on themselves, and then allow a finger sample to be obtained for accuracy validation versus the YSI reference instrument. Subjects were observed by health care professionals (HCPs) to assess their ease of use of the POGO BGMS, and were also asked to complete questionnaires to assess their understanding of the labeling and their self-reported ease-of-use of the system, as well as provide a comparison between the POGO BGMS and their current BGMS. HCPs also performed assisted fingerstick tests on subjects meeting pre-specified criteria for accuracy verification versus the YSI reference instrument. During the studies, no adverse events were reported.

During user self-testing for system accuracy validation, a total of 100% of POGO BGMS self-test glucose results were within ± 15 mg/dL of the reference YSI results at a glucose concentration of < 75 mg/dL. At glucose concentrations of ≥ 75 mg/dL, 95.8% of POGO BGMS self-test glucose results were within 15% of the reference YSI and 99.1% of POGO BGMS results were within ± 20 % of the reference YSI.

For the HCP results (accuracy verification), 94.4% of the POGO BGMS glucose results were within ± 15 mg/dL of the reference YSI results at a glucose concentration of < 75 mg/dL. At glucose concentrations of ≥ 75 mg/dL, 96.1% of POGO BGMS accuracy verification results were within 15% of the reference YSI and 98.5% of POGO BGMS results were within ± 20 % of the reference YSI.

A total of 92.3% of patients found the POGO BGMS easy to use, and 96.5% of the subjects were capable of using POGO BGMS, including all steps required to correctly perform a test, as evaluated by a trained HCP. 91.9% of subjects found the instructions easy to understand. Also, at least 72% of subjects “agreed” or “strongly agreed” that POGO BGMS was easier to use than their current BGMS and > 80 % of the subjects felt that the POGO BGMS was more convenient than their current BGMS. A majority, 51%, of subjects agreed that they would better adhere to their healthcare professional’s recommended testing schedule using the POGO BGMS and > 81 % of subjects either agreed or strongly agreed that they would recommend POGO BGMS to a friend.

11 Conclusions from Nonclinical and Clinical Testing

Results from the nonclinical and clinical testing using the POGO Blood Glucose Monitoring System demonstrate that the POGO BGMS is substantially equivalent to the predicate devices. The POGO BGMS is safe and effective for its intended use and performs as well as or better than the predicate devices.