



Food and Drug Administration
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April 6, 2017

INTUITY MEDICAL, INC.
C/O CINDY DOMECUS, R.A.C.
PRINCIPAL, DOMECUS CONSULTING SERVICES, LLC
1171 BARROILHET DRIVE
HILLSBOROUGH, CA 94010

Re: K162203

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
Dated: February 28, 2017
Received: March 1, 2017

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 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,


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

Indications for Use

510(k) Number (if known)
k162203

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

1 510(k) Owner

Owner: Intuity Medical, Inc.
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 Sunnyvale, CA 94085
Phone: (408) 530-1700 x275
Fax: (408) 530-1717
Contact: Robb Hesley

2 Submission Correspondent:

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

3 Date Summary Prepared: February 28, 2017

4 Device name - trade name and common 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, CGA
Panel	Clinical Chemistry

5 Identification of the legally marketed predicate device

The POGO® Automatic™ Blood Glucose Monitoring System is substantially equivalent to the Contour Next EZ Blood Glucose Monitoring System (Bayer HealthCare LLC, Mishawaka, IN), cleared under k130265 on June 23, 2014.

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. 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 strip to obtain a glucose result rather than an error. 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.

8 Technological Characteristics Comparison

Characteristic	POGO BGMS	Contour Next EZ k130265
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. 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 Automatic Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.</p>	<p>The Contour Next EZ blood glucose monitoring system is an over the counter (OTC) device utilized for self-testing by persons with diabetes at home for the quantitative measurement of glucose in whole blood, is for single-patient use only, and should not be shared. The Contour Next EZ blood glucose monitoring system is indicated for use with fresh fingertip capillary whole blood samples. The clinical utility of this device is to aid in monitoring the effectiveness of your diabetes control program. The Contour Next EZ blood glucose monitoring system is not intended for use for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Contour Next test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL.</p>
Rx/OTC	OTC	Same

Characteristic	POGO BGMS	Contour Next EZ k130265
Classification Regulation	862.1345	Same
Product Codes	NBW, CGA	NBW, LFR
Product Design	Battery-powered handheld meter	Same
Delivery of Blood to Reagent Pad via Capillary Action	Yes	Same
Automatic Blood Sample Collection	Yes	No
Detects Under-filled Reagent Pad	Yes	Same
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	20 seconds
Time period allowed for patient to apply blood when blood does not reach reagent pad	90 seconds	180 seconds
Meter enforces limits on strip exposure?	Yes, device design prevents strip use after 5 minute exposure (open cell time window)	No, device design does not prevent strip re-insertion unless blood or serious mishandling is detected
Patient able to re-use lancet?	No, device design prevents re-use	Yes, device design does not prevent re-use
Cal Coding	Automated	Same
Detection Method	Photometric (LED)	Electrochemical
Enzyme	Glucose oxidase	Glucose dehydrogenase
Hematocrit Range	20% to 60%	15% to 65%
Humidity Range	10% to 90% RH	10% to 93% RH

Characteristic	POGO BGMS	Contour Next EZ k130265
Lancing Device	Integrated in Meter with Strip/Lancet in Cartridge	Separate from Meter
Measurement Range	20 - 500 mg/dL	20 - 600 mg/dL
Minimum Sample Size	0.25 µL	0.6 µL
Monitor Memory	500 results	480 results
Operating Temperature Range	50 to 104° F	41 to 113° F
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 glucose dehydrogenase-FAD and electrons are transferred to form a reduced mediator intermediate. The reduced mediator transfers electrons to an electrode to produce an electric current, which is proportional to the concentration of glucose in the sample. The current is read by a potentiometer in the meter.

Comparison of Intended Use

POGO BGMS and the listed predicate device have the same intended use; namely, the quantitative measurement of blood glucose. Both devices use fingerstick capillary whole blood as the sample. Both devices are for single-patient use in the home.

Comparison of Technological Characteristics

The technology used in the POGO BGMS is similar to that used in the predicate device. Similar elements include: a capillary channel to automate blood delivery from the fingerstick wound to the reagent section of the test strip, a means to detect when an insufficient amount of blood has been applied to the test strip, and the ability to add blood to an in-process test until either the meter has sufficient sample or the time allowed to add blood has expired. 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 different signal transduction system (photometric in POGO BGMS, electrochemical in 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 μ L versus 0.6 μ L in the 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. The POGO BGMS also prevents use of a test strip that has been exposed to the environment for more than five minutes (open cell time window), whereas the predicate device has no means to measure strip exposure time and does not prevent strip re-insertion until the strip contains blood or has been seriously degraded by moisture.

9 Brief Discussion of Nonclinical Data

The software change that is the subject of this 510(k) was validated.

In accordance with FDA's *Guidance for Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use*, issued in October, 2016, IMI obtained 60 POGO BGMS whole blood results via intermittent sampling at nominal glucose levels from 60 to 225 mg/dL. All data were within $\pm 15\%$ bias to the plasma YSI reference results.

10 Brief Description of Clinical Data

In support of the Reapplication feature of the POGO BGMS, Intuity Medical, Inc. (IMI) has conducted three clinical studies. The initial study was a multi-site Clinical Lay User Evaluation where some of the system accuracy data was from users who completed the test using Reapplication. The two subsequent studies focused on collecting additional data specifically from the system in the Reapplication Mode using native fingerstick capillary whole blood samples.

In the Clinical Lay User Evaluation, self-test data from 285 subjects with diabetes, from a total of four cartridge lots, were evaluated for accuracy versus plasma from a fingerstick sample analyzed on a YSI. 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 for both Automated and Reapplication results. At glucose concentrations of ≥ 75 mg/dL, 95.0% of POGO BGMS self-test glucose results were within $\pm 15\%$ of the reference YSI (95.8% Automated and 91.5% Reapplication) and 99.2% of POGO BGMS results were within $\pm 20\%$ of the reference YSI (99.1% Automated and 100% Reapplication). These results met the predetermined accuracy specifications.

Following the Clinical Lay User Evaluation, additional clinical studies were conducted where lay users tested with the POGO BGMS in Reapplication Mode to evaluate the accuracy of the POGO BGMS glucose result versus a YSI reference. A total of 215 data points were obtained over a range of native glucose levels from 48 to 396 mg/dL. The overall results from each study demonstrated at least 95% of results within 15%

(for glucose \geq 75mg/dL) or 10 mg/dL (for glucose < 75mg/dL) of the YSI. These studies confirmed that the POGO BGMS provides accurate results when used in the Reapplication Mode.

11 Conclusions from Nonclinical and Clinical Testing

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