510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k152493

B. Purpose for Submission:
New Device

C. Measurand:
Capillary whole blood glucose from the fingertip

D. Type of Test:
Quantitative Amperometric assay (Glucose Oxidase)

E. Applicant:
Intuity Medical, Inc.

F. Proprietary and Established Names:
POGO Automatic Blood Glucose Monitoring System

G. Regulatory Information:

Regulation Section	Classification	Product Code	Panel
21 CFR 862.1345	Class II	CGA, Glucose Oxidase,	Clinical Chemistry (75)
21 CFR 862.1345	Class II	NBW, System, Test, Blood Glucose, Over the Counter	Clinical Chemistry (75)
21 CFR 862.1660	Class I (exempt)	JJX, Quality Control Material (assayed and unassayed)	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indication(s) for use below.

2. Indication(s) 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 (ages 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.

3. Special conditions for use statement(s):

- For in vitro diagnostic use
- The POGO Automatic System is not intended for multi-patient use. Do not use on more than one patient in a clinical setting such as hospitals, long-term care, assisted living facilities, clinics or health fairs as this might pass infection from one patient to another.
- The POGO Automatic System is not intended for the quantitative measurement of venous or arterial blood.
- The POGO Automatic System is not intended for use on neonates.
- The POGO Automatic System should not be used for the diagnosis of or screening of diabetes.
- The POGO Automatic Meter should only be used with POGO Automatic Test Cartridges and POGO Control Solutions.
- Individual test cells and cartridges are single use only. Do not attempt to reuse.
- Use only fresh whole capillary blood. Do not attempt to use plasma or serum to obtain an accurate blood glucose test result.
- Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill or in a hyperosmolar state.
- The hematocrit range for the POGO Automatic System is 20% – 60%. Extremely high hematocrit levels above 60% may cause falsely low results and very low hematocrit levels below 20% may cause falsely high results.
- The POGO Automatic System has not been evaluated at altitudes above 10,000 feet.

- **WARNING:** Each lancet is coated with a tiny amount of heparin (<0.24 IU) which keeps the collected blood from clotting inside the test cell until your results appear. Before using this device, let your doctor know if you are allergic to heparin or have ever been diagnosed with Heparin- Induced Thrombocytopenia, also known as HIT. HIT is a very rare condition which causes blood clots. Stop using the device and contact your doctor if you notice unexplained swelling in one arm or leg, sudden severe chest pain or shortness of breath, or stroke symptoms.

4. Special instrument requirements:

   POGO Automatic Meter

I. Device Description:

The POGO Automatic Blood Glucose Monitoring System consists of the POGO Automatic Meter, disposable POGO Automatic Test Cartridges (10 tests per cartridge; glucose oxidase from *Aspergillus*), and 2 levels of ready-to-use control solution wands (POGO Control Solution, Level 1 and Level 2).

The POGO BGMS automatically lances, collects the blood sample and transports the sample via capillary action to an internal test strip inside the disposable cartridge to measure blood glucose. The meter also includes a vacuum pump to assist in sample collection.

The 10-test Test Cartridge includes 10 individually foil-sealed hollow lancets, springs, and test strips. The lancing mechanism is built into individual test cells of the cartridge. The used tests (test strips and lancets) are retained within the cartridge.

Two levels of control solution are provided as wands for use with the POGO Automatic Blood Glucose Monitoring System, POGO Control Solution Level 1 and Level 2.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ACCU-CHEK Compact Plus Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k081389

3. Comparison with predicate:

Similarities and Differences		
Item	**Predicate Device** ACCU-CHEK Compact Plus Blood Glucose Monitoring System, K081389	**Candidate Device** POGO Automatic Blood Glucose Monitoring System
Intended Use/Indications for Use	Same	For quantitative measurement of glucose in whole blood
Intended use population	No age restrictions	Adults and adolescents, ages 13 and up
Use Setting	At home for single patient use only	Same
Detection method	Same	Photometric (LED)

Enzyme	Glucose Oxidase	Glucose Dehydrogenase
Calibration Coding	Same	Automated
Memory	Same	500 test results
Test range	10-600 mg/dL	20-500 mg/dL
Sample type	Capillary and venous whole blood	Capillary whole blood
Sample sites	Finger, forearm, upper arm, thigh, calf and palm	fingertip
Sample volume	0.6 µL	0.25 µL
Hematocrit range	25-65%	20-60%
Power Source	Same	2 AAA batteries

Similarities and Differences for Control Solutions		
Item	**Predicate Device** Glucose Meter-Check Solution Roche ACCU-CHEK, k123851	**Candidate Device** POGO Control Solutions
Intended use/Indications for Use	Intended to assess performance of Roche ACCU-CHEK blood glucose monitoring systems	Used with POGO BGMS to indicate appropriate user technique and to indicate that the test cartridge and meter are functioning properly.
Matrix	Same	Water, buffer, salts, viscosity modifier, glucose, preservatives, dyes
Number of levels	One level	Two levels, Level 1 and Level 2

K. Standard/Guidance Document Referenced:

- AAMI/TIR12: 2010, Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.
- AAMI/TIR30: 2011, A compendium of processes, material, test methods, and acceptance criteria for cleaning reusable medical devices.
- ASTM D4169-14: 2014, Standard Practice For Performance Testing of Shipping Containers and Systems.
- EN 61326-1: 2006 Electrical Equipment for Measurement, Control and Laboratory Use-EMC Requirements.
- EN 61326-2-6: 2006 Electrical Equipment for Measurement, Control and Laboratory Use. Particular requirements. In vitro diagnostic (IVD) medical equipment
- IEC 60068-2-64: 1993, Environmental testing – Part 2: Test methods – Test Fh:

Vibration, broad-band random (digital control) and guidance.

- IEC/EN 61010-1: 2001 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Part 1: General Requirements.
- ISO 10993-1:2009, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management system.
- ISO 10993-10: 2010, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity.
- ISO 10993-12: 2012, Biological evaluation of medical devices-Part 12: Sample preparation and reference materials.
- ISO 10993-5: 2009, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity
- ISO 11607-1: 2006, Packaging for terminally sterilized medical devices – Part 1.
- EN 11737-1: 2006, Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products
- EN 11737-2: 2009, Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the validation of a sterilization process

L. Test Principle:

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 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.

M. Performance Characteristics:

a. Precision/Reproducibility

The sponsor performed repeatability studies using venous whole blood samples spiked with five different glucose concentrations (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 mg/dL). Each glucose level was analyzed in replicates of 10, with 3 cartridge lots, and 10 meters for a total of 300 tests per each glucose level. Results are summarized below:

Repeatability precision summary:

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 to 50	300	41.8	1.4	3.4
51 to 110	300	102.9	2.7	2.6
111 to 150	300	136.5	3.1	2.3
151 to 250	300	204.1	5.0	2.5
251 to 400	300	335.8	7.9	2.6

Intermediate precision was evaluated using three levels of glucose control solutions with concentrations of approximately 30, 100 and 300 mg/dL. Each sample was measured in duplicate with three test strip lots and 10 Rightest GM700 meters. These tests were performed over 20 days, for a total of 600 tests per glucose level. Results are summarized below.

Intermediate precision summary:

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	% CV
30	600	32.8	2.1	5.6
100	600	96.2	3.0	3.1
300	600	288.9	9.3	3.2

b. Linearity/assay reportable range:

Linearity was evaluated using three test strip lots and 9 mixed pools of venous blood samples ranging in glucose concentrations of 19.8, 40.5, 79.3, 117, 164, 207, 289.5, 424, and 528.5 mg/dL as measured by YSI 2300. Each level was measured in replicates of 5 and the values from the POGO Automatic Meter were compared with those obtained from YSI 2300. Results from regression analysis:

Test strip lot #1: $y = 0.9751x + 1.73$; $R^2 = 0.996$
Test strip lot #2: $y = 1.005x – 1.42$; $R^2 = 0.997$

The results of the study support the sponsor's claimed glucose measurement range of 20 500 mg/dL.

The sponsor demonstrated that the meter reads 'LO' when glucose test results are <20 mg/dL and 'HI' when they are >500 mg/dL, as intended.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability
The POGO Automatic Blood Glucose Monitoring System is traceable to NIST SRM 917c. The method comparison study was performed using the candidate device and YSI as the reference method (see Section M.3.c)

Test Strip (Cartridge) Stability:
Test strip cartridge stability was assessed in accelerated and real time studies. Testing protocols and acceptance criteria for the POGO Automatic Test Cartridges were reviewed and found to be acceptable. The manufacturer claims shelf life stability of 12 months and an open-vial stability of 60 days at the recommended storage temperatures of 40°F-86°F (4°C-30°C) and 10-90% RH.

Open cartridge cell function

The sponsor performed an open test tolerance to evaluate the open cartridge cell performance. The POGO system was used to test venous blood samples at 80 mg/dL and 320 mg/dL glucose concentrations after the following sequence: at various time points (1, 5, 10 and 15 minutes) following the opening of the test cell by the meter, blood was then applied to the lancet. Acceptable bias was demonstrated between meter results and the reference method (YSI) to support the 5 minute open cartridge cell function of the POGO system.

Control Solution Value assignment and Stability:

Value assignment:

Each Control Solution level is tested twenty times on each cartridge lot and the average of the POGO results from those replicates is used as the "calibration code control mean" for that cartridge lot. The assigned calibration code control means (glucose values) are recorded in the barcode that is placed on each cartridge in the lot. The POGO meter calculates the control range for each level as ±15% of its calibration code control mean, as read from the cartridge barcode.

Control Solution Stability:

Stability was assessed using real-time and accelerated testing for each control solution level. Protocols and acceptance criteria were reviewed and found to be acceptable to support the shelf life stability claim of 12 months when stored at the recommended storage temperatures of 40°F-86°F (4°C-30°C).

The control solution wands are single-use therefore, open-vial stability claims are not necessary.

d. Detection limit:

The reportable range is 20 to 500 mg/dL based on linearity studies above (section M.1.b.).

e. Analytical specificity:

Interference studies were performed by spiking venous blood with two levels of glucose concentrations (80 and 320 mg/dL). Each of these samples was divided into a test pool and a control pool and each potential interfering substances was added to the test pool. Each compound was tested at two concentrations, normal/therapeutic and high/toxic concentrations and each sample was analyzed in replicates of 10 with the POGO Automatic meter. The % difference between the test sample and the control sample was calculated. Results are presented in the table below:

Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)		Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)
Acetaminophen	20		Ibuprofen	50
Acetylsalicylic Acid	65		L-Dopa	2.8
Ascorbic Acid	3		Maltose	500
Bilirubin, conjugated	20		Methyldopa	1.5
Cholesterol	753		Salicylate	60
Creatinine	5		Tolazamide	40
Dopamine	0.11		Tolbutamide	64
Galactose	10		Triglycerides	3000
Gentisic acie	2.06		Uric Acid	9
Glutathion, Reduced	93.7		Xylose	200
Hemoglobin	2000		Sugar Alcohols	0.9

The labeling includes the following:

If you have certain conditions that may cause your blood level of uric acid to rise,such as gout or kidney disease (>9 mg/dL uric acid) then your blood glucose results may be inaccurate. If you are unsure, then ask your doctor.

If you are taking acetaminophen containing drugs (e.g. Tylenol, certain cold and flu remedies etc.) in excess of the recommended levels (>20 mg/dL) then you may get inaccurate results with this system. If you are unsure, then ask your doctor.

If you are taking vitamin C (ascorbic acid) in excess of the recommended levels >3 mg/dL, then your glucose results may be inaccurate with this system. If you are unsure, then ask your doctor.

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device

See lay user study in section M.3.c

b. Matrix comparison:

Not applicable

3. Clinical studies:
   a. Clinical Sensitivity:

   Not applicable

   b. Clinical specificity:

   Not applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

   User performance study:
   To assess the performance of the POGO Automatic Blood Glucose Monitoring System in the hands of the intended users the sponsor performed a study with 233 lay-user participants who performed testing of fingerstick capillary samples using the POGO system unassisted. Meter results were compared to capillary fingerstick blood glucose results obtained on a reference analyzer (YSI). Glucose concentrations ranging from 46.5 mg/dL to 437 mg/dL were tested using three test strip lots. The results relative to YSI are summarized in the tables below:

   Lay user vs YSI

   For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
2/9 (22.2%)	9/9 (100.0%)	9/9 (100.0%)

   For glucose concentrations ≥ 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
111/214 (51.9%	178/214 (83.2%)	205/214 (95.8%)	212/214 (99.1%)

   Linear Regression Analysis:
   $y = 0.9754x + 7.3764$; $R^2 = 0.9730$; N=223

Control solution usability study:
To assess the ability of users to understand the labeling and properly use the control solution wands the sponsor performed a usability study with 29 lay-users. The participants were provided with an excerpt from the Control Solution section of the POGO Owner's Manual and asked to perform a control solution without assistance to obtain a result, "P" (Pass) or "F" (Fail). The study was followed by followed by participants followed by a questionnaire an assessment of the subject's testing performance by the study staff. The study demonstrates the subjects were able to use the control solution wands to obtain a 'result' using the labeling.

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:
   In the labeling the sponsor presents expected blood glucose levels for people without diabetes as:
   Fasting <100mg/dL
   2 Hours After Start of Meal <140 mg/dL

   These ranges were cited from the American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 31:S55-S60, 2016.

N. Instrument Name:

POGO Automatic Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 250 nL

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ____X____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No __X____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes __X___ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test cartridge as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the fingertip only. The whole blood sample is applied directly to the test pad through the lancet in the test cartridge by capillary action.

5. Calibration:

   The meter does not require calibration or coding by the user.

6. Quality Control:

   Two pre-filled, single-use control solution wands are provided with the POGO System (POGO Control Solutions Level 1 and Level 2). The wands have a foil-sealed reservoir at the end that is inserted into the meter test port. The meter automatically detects whether the sample is blood or control solution and distinguishes from Level 1 and Level 2. The meter uses the cartridge barcode information to evaluate the calculated control result to display a P (pass) or F (fail). Different cartridge lots have different levels encoded on the barcode.

   Up to 500 user-accessible test results can be stored. Results are stored automatically and identified by the meter as either a user glucose reading or a control solution result that the meter determines by detecting the signature of a dye added to the control solution. The meter also allows previous test results to be recalled and displayed individually or averaged (for example, 7, 14 or 30 day averages of glucose test results).

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Hematocrit Study: The effect of different hematocrit levels on the performance of the POGO Automatic Blood Glucose Monitoring System was evaluated using venous whole blood to seven hematocrit levels (20%, 25%, 30%, 40%, 50%, 55%, and 60%) spiked with glucose to achieve 4 concentrations (60, 120, 250 and 400 mg/dL). Each sample was then tested in replicates of 5 using the POGO Automatic Meters and 3

cartridge lots and the values were compared with those obtained from YSI 2300 analyzer. The % biases relative to YSI were acceptable within the claimed hematocrit range and support the claimed hematocrit range of 20 to 60%.

2. Altitude Study:
   Venous whole blood samples were adjusted to obtain 3 glucose concentrations (60, 120 and 300 mg/dL) were tested at 36, 5333 and 10,407 feet above sea level. Each blood sample was tested using the POGO Automatic Blood Glucose Monitoring System in replicates of five at each elevation and results were compared to YSI values. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,000 feet above sea level have no significant effect on blood glucose measurements when using the POGO Automatic Blood Glucose Monitoring System.

3. Sample volume study:
   The sponsor performed a study to verify the test strip sample volume requirement for the POGO Automatic Blood Glucose Monitoring System. Blood samples (60, 120 and 300 mg/dL glucose) were tested at five sample volumes (150 nL, 200 nL, 250 nL, 300 nL, and 1000 nL) and values obtained were compared to YSI values. Results support the claimed sample volume of 250 nL and the error code for insufficient sample volume.

4. Operating conditions study:
   The sponsor performed temperature and humidity studies using venous blood samples adjusted to three glucose concentrations (60, 120 and 300 mg/dL) to evaluate temperature and humidity conditions ranging from 50°F to 104°F (10°C to 40°C) and relative humidity from 10% to 90%. Each condition and glucose concentration was tested in replicates of 10. Meter results were compared to YSI values. Six temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, average temperature/low humidity, average temperature/high humidity, high temperature/low humidity, and high temperature/high humidity. No significant effect (relative to YSI) was observed with the temperature and humidity combinations tested. The results support the claims in the labeling that the system can be used in conditions of 50°F to 104°F (10°C to 40°C) with relative humidity of 10 to 90%.

5. Readability Assessment:
   The readability of the labeling (user manual, test strip package insert and control solution package insert) was evaluated using a Flesch-Kincaid analysis and was found to be at the 8th grade level.

6. EMC Testing:
   The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed and the System was found compliant.

7. Software documentation:
   The software documentation was reviewed and found to be acceptable. The firm provided documentation to support the device was designed, developed and is under good software lifecycle processes

8. Infection Control Studies:
   The device system is intended for single-patient use. Cleaning and disinfection efficacy studies were performed demonstrating that the meter interior and exterior can be cleaned and disinfected using Clorox Germicidal Wipes (EPA Reg. No. 67619-12). Robustness studies were also performed by the sponsor using the POGO Automatic Blood Glucose Monitoring System and demonstrating that there was no change in performance of the system or internal and external materials of the meter after 730 cleaning and disinfection cycles, using the chosen disinfectant, to simulate cleaning and disinfecting the meter (exterior and interior) every 1.5 day over the 3 years use life to support cleaning and disinfection after each test cartridge use (10 tests per cartridge). Robustness testing was also performed to support 1100 cleaning and disinfection cycles for the removable test platform to support cleaning and disinfecting every day. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.