

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

**A. 510(k) Number:**

k162203

**B. Purpose for Submission:**

Device modification to add a reapplication feature to previously cleared device (k152493)

**C. Measurand:**

Capillary whole blood glucose from the fingertip

**D. Type of Test:**

Quantitative Photometric 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) |

**H. Intended Use:**

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

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, previously cleared in k152493).

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 device has been modified by adding a reapplication feature, the ‘add more blood’ feature to the previously cleared device (k152493). This reapplication feature detects when the sample volume is underfilled and when no blood reaches the test pad, and allows the user 15 or 90 seconds (respectively) to add blood to the test strip.

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.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Contour Next EZ Blood Glucose Monitoring System
  
2. Predicate 510(k) number(s):  
K130265
  
3. Comparison with predicate:

| <b>Similarities and Differences</b>  |  |   |
|--------------------------------------|--|---|
| <b>Item</b>                          | <b>Predicate Device</b><br>Contour Next EZ<br>Blood Glucose<br>Monitoring System,<br>k130265 | <b>Candidate Device</b><br>POGO Automatic<br>Blood Glucose<br>Monitoring System |
| Intended Use/<br>Indications for Use | Same   | For quantitative<br>measurement of glucose<br>in whole blood                    |
| Intended use<br>population           | No age restrictions  | Adults and adolescents,<br>ages 13 and up                                       |
| Use Setting                          | Same   | At home for single<br>patient use only  |
| Detection method                     | Electrochemical  | Photometric (LED)   |
| Enzyme                               | Glucose<br>Dehydrogenase   | Glucose Oxidase   |
| Calibration Coding                   | Same   | Automated   |
| Memory                               | 480 test results   | 500 test results  |

|                              |              |                       |
|------------------------------|--------------|-----------------------|
| Test range                   | 20-600 mg/dL | 20-500 mg/dL          |
| Sample type                  | Same         | Capillary whole blood |
| Sample sites                 | Same         | Fingertip             |
| Sample volume                | 0.6 µL       | 0.25 µL               |
| Hematocrit range             | 15-65%       | 20-60%                |
| Short sample detection       | No           | Yes                   |
| Sample Reapplication ability | Yes          | Yes                   |

#### **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.
- IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- 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
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#### **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:**

### **1. Analytical performance**

#### *a. Precision/Reproducibility*

Established in k152493

#### *b. Linearity/assay reportable range:*

Established in k152493

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

##### Traceability

The POGO Automatic Blood Glucose Monitoring System is traceable to NIST SRM 917c.

##### Test Strip (Cartridge) Stability:

Test strip cartridge stability protocols and acceptance criteria for the POGO Automatic Test Cartridges were reviewed and found to be acceptable in k152493. The manufacturer claims shelf life stability of 12 months and an open-vial stability of 45 days at the recommended storage temperatures of 40°F-86°F (4°C-30°C) and 10-90% RH.

##### Open cartridge cell function

Reviewed and found acceptable in k152493.

##### Control Solution Value assignment and Stability:

Value assignment and stability protocols and acceptance criteria for the control solutions were reviewed and found to be acceptable in k152493. The manufacturer claims shelf life stability 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 package stability claims were not necessary.

#### *d. Detection limit:*

The reportable range is 20 to 500 mg/dL based on linearity studies reviewed in k152493.

e. *Analytical specificity:*

Established in k152493

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device*

Established in k152493

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:**

Established in k152493

**Reapplication feature:**

The sponsor conducted a clinical lay user evaluation in support of the device reapplication feature. In this study, 85 subjects performed capillary fingertip self-testing with the POGO device, using only the product labeling materials, followed by healthcare professionals obtaining a capillary sample from each subject and running the samples on the YSI. The glucose concentration range was 32 to 398 mg/dL. Out of the 285 tests, the POGO device identified 54 short samples, required reapplication. The glucose concentrations of these 54 samples were 42-365 mg/dL. The results relative to YSI are summarized below:

**For glucose concentrations <75 mg/dL**

|                     |                      |                      |
|---------------------|----------------------|----------------------|
| within<br>± 5 mg/dL | within<br>± 10 mg/dL | within<br>± 15 mg/dL |
| 1/7 (14.3%)         | 5/7 (71.4%)          | 7/7 (100.0%)         |

**For glucose concentrations ≥ 75 mg/dL**

|                  |                  |                  |                   |
|------------------|------------------|------------------|-------------------|
| 5%               | within<br>± 10 % | within<br>± 15 % | within<br>± 20 %  |
| 17/47<br>(36.2%) | 36/47<br>(76.6%) | 43/47<br>(91.5%) | 47/47<br>(100.0%) |

Linear Regression Analysis:

$$Y = 0.981x + 10.369, R^2 = 0.9631, N = 54$$

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 39: Supplement 1, S1-S112, 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 0.25 uL

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

Yes  or No

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

Yes  or No

2. Software:

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

Yes  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, previously cleared in k152493). 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:  
Established in k152493
2. Altitude Study:  
Established in k152493
3. Sample volume study:  
Established in k152493
4. Operating conditions study:  
Established in k152493
5. Readability Assessment:  
Established in k152493
6. EMC Testing:  
Established in k152493
7. Software documentation:  
The software documentation was reviewed and found to be acceptable. The firm provided documentation to support the device modification did not affect the performance of the device. There are two error messages associated with the reapplication feature of the device: “E-4” and “NO”, with a blood droplet icon. “E-4” indicates that blood is detected on the test pad, but not enough blood has been applied. “NO”, with a blood droplet icon, indicates that no blood is detected on the test pad. The sponsor provided adequate verification and validation that the re-app mode and associated error messages functioned as intended.
8. Infection Control Studies:  
Established in k152493. No physical modifications are being made to the device, therefore no cleaning, disinfection or robustness need to be redone.

The device system is intended for single-patient use. Cleaning and disinfection efficacy studies were performed in k152493 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.

9. This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to the finalization of the guidance documents.

**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.