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

A. 510(k) Number:

k152365

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:

AgaMatrix Inc.

F. Proprietary and Established Names:

AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 Blood Glucose Test System	Clinical Chemistry 75
CGA	Class II	21 CFR 862.1345 Glucose Oxidase, Glucose	Clinical Chemistry 75

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:
   The AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose (sugar) levels in fresh capillary whole blood samples drawn from the fingertip. It is intended to be used by a single patient and should not be shared. The AgaMatrix Jazz Wireless 2 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 AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

   The AgaMatrix Jazz Blood Glucose Test Strips are for use with the AgaMatrix Jazz Wireless 2 Blood Glucose 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
   - It is intended to be used by a single person and should not be shared.
   - Do not use for the diagnosis of or screening of diabetes mellitus
   - Do not use for patients who are dehydrated, hypotensive, in shock critically ill or in a hyper-osmolar state
   - Do not use for persons undergoing Oxygen therapy
   - Do not use for testing glucose levels in neonates
   - Do not use for testing glucose levels in arterial or venous blood samples
   - Do not use for testing glucose from sites other than samples drawn from the fingertip

4. Special instrument requirements:

   AgaMatrix Jazz Wireless 2 Blood Glucose Meter

I. Device Description:

The AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System includes the Jazz™ Wireless 2 Blood Glucose Meter and the Jazz Glucose Test Strips. The Agamatrix Glucose Control Solutions, Levels 2 and 4, are available for use with this system, but not included. The Jazz Glucose Test Strips and Agamatrix Glucose Control Solutions were previously cleared in k103554.

The AgaMatrix Jazz Wireless 2 Blood Glucose Meter has Bluetooth capability for communication with appropriate iOS or Android (minimum operating system requirements: iOS7 or Android 5.1) software application. The AgaMatrix Diabetes Manager Mobile Application, cleared in k132821, is compatible for use with this system.

The following items are included in the AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System:

- AgaMatrix Jazz Wireless 2 Glucose Meter

- Two Pre-installed CR2032, 3 Volt, Lithium Batteries
- Owner's Guide
- AgaMatrix Jazz Test Strip Insert
- Compact Carrying Case
- AgaMatrix Lancing Device
- 10 AgaMatrix Lancets
- 1 Vial of 10 AgaMatrix Jazz Blood Glucose Test Strips
- Meter Pairing & Syncing Guide

J. Substantial Equivalence Information:

1. Predicate device name(s):

   iBGStar Blood Glucose Monitoring System

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

   k103544

3. Comparison with predicate:

Similarities		
Item	Predicate Device iBGStar Blood Glucose Monitoring System (k103544)	Candidate Device AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System
Intended Use/Indications for Use	Intended to be used for quantitative measurement of glucose in fresh capillary whole blood, as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Detection method	Dynamic Electrochemistry	Same
Enzyme	Glucose Oxidase	Same
Calibration Coding	Non-Coding	Same
Sample Type	Capillary whole blood	Same
Sample volume	0.5 µL	Same

Similarities		
Item	Predicate Device iBGStar Blood Glucose Monitoring System (k103544)	Candidate Device AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System
Average test time	5 seconds	Same
Operating Temperature	50° - 104°F	Same
Measurement Range	20 to 600 mg/dL	Same
Calibration	Plasma Equivalent	Same
Control levels	Level 2 and Level 4	Same
Hematocrit range	20 - 60%	Same
Altitude claim	Up to 10,000 feet	Same

Differences		
Item	Predicate Device iBGStar Blood Glucose Monitoring System (K103544)	Candidate Device AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System
Sample sites	Finger, forearm, upper arm and palm	Fingertip
Operating Humidity	Up to 90%	10% - 90%
Connectivity	Meter utilizes a 30-pin dock connecter to directly connect to iPhone/iPod touch or Apple Lightning Adapters.	Meter has Bluetooth capability for communication with appropriate iOS or Android software application (minimum operating system requirements of iOS7 or Android 5.1)
Meter size	L-56 mm, W-24 mm, H-10 mm	L-65 mm, W-30 mm, H-10 mm

Differences		
Item	Predicate Device iBGStar Blood Glucose Monitoring System (K103544)	Candidate Device AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System
Weight	8.5 g	18 g
Number of results stored	300	300
Power Source	A polymer lithium-ion rechargeable battery	(2) replaceable CR2032 3 volt, lithium batteries

K. Standard/Guidance Document Referenced (if applicable):

ISO 14971:2007: Medical devices - Application of risk management to medical devices

EP07-A2: Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2005).

EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).

IEC 60601-1-2: Medical Electric Equipment: General Requirements for Basic Safety and Essential Performance

L. Test Principle:

The AgaMatrix Jazz Glucose Test Strip contains the glucose oxidase (GOx) enzyme with a redox chemical mediator that produces an electrochemical signal in proportion to the glucose concentration in the blood sample. The AgaMatrix Jazz Wireless 2 meter measures this signal, using dynamic electrochemistry to correct for common analytical interferences such as hematocrit.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

   Within run precision was evaluated using venous blood samples depleted or spiked to five different glucose concentrations across the system measuring range (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL). Each sample was tested on three lots of test strips using 12 meters per test strip lot. Ten

replicates were tested per meter, test strip lot and glucose concentration. Results are summarized in the table below:

Strip Lot 1

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
n	118	120	120	120	120
Mean (mg/dL)	34.8	100.8	132.9	220.1	388.0
Std Dev (mg/dL)	2.4	3.2	2.6	6.5	9.9
CV (%)	6.9	3.2	2.0	2.9	2.5

Strip Lot 2

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
n	119	120	120	120	120
Mean (mg/dL)	31.3	96.4	129.3	221.1	379.9
Std Dev (mg/dL)	1.6	3.9	4.2	7.2	16.3
CV (%)	5.3	4.0	3.3	3.5	4.3

Strip Lot 3

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
n	119	120	120	120	120
Mean (mg/dL)	30.6	96.9	128.5	229.5	380.4
Std Dev (mg/dL)	2.6	4.0	3.9	5.0	17.3
CV (%)	8.5	4.1	3.0	2.2	4.0

Intermediate (day-to-day) precision was evaluated by sampling glucose control solutions at three different glucose concentration levels. Each sample was tested on three lots of test strips on ten meters by each of three operators, on each of ten days. Ten measurements were made on each meter per strip lot for each level; this resulted in 30 measurements per meter per level. The results are summarized in the table below:

Strip Lot 1

Glucose conc. (mg/dL)	Level 1	Level 2	Level 4
Mean (mg/dL)	57.1	134.0	343.5
Std Dev (mg/dL)	1.6	3.4	8.5
CV (%)	2.8	2.6	2.5

Strip Lot 2

Glucose conc. (mg/dL)	Level 1	Level 2	Level 4
Mean (mg/dL)	57.8	137.9	345.5
Std Dev (mg/dL)	2.2	2.9	8.8
CV (%)	3.7	2.1	2.6

Strip Lot 3

Glucose conc. (mg/dL)	Level 1	Level 2	Level 4
Mean (mg/dL)	57.1	134.3	342.5
Std Dev (mg/dL)	1.8	3.1	7.4
CV (%)	3.1	2.3	2.2

b. Linearity/assay reportable range:

Linearity was evaluated using three test strip lots and twelve prepared venous blood samples. Glucose concentrations of the samples, as determined by YSI reference method, were 18, 48, 78, 137, 196, 255, 314, 373, 432, 492, 551 and 610 mg/dL. For each glucose concentration, twelve replicates were tested for each lot of test strips. The mean of values from the device were compared with those obtained from the YSI reference method. The results from regression analysis are summarized below:

Lot 1: $y = 1.02x - 0.90$, $R^2 = 1.00$
Lot 2: $y = 1.00x + 0.94$, $R^2 = 1.00$
Lot 3: $y = 1.01x - 0.05$, $R^2 = 1.00$

The results of the study support the claimed glucose measurement range of 20 mg/dL to 600 mg/dL.

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

Traceability:

The AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System is traceable to the NIST SRM 917c glucose reference material. The method comparison study was performed using the candidate device and YSI as the reference method (see Section 2.a.).

Stability:

Test strip stability:
Stability of the AgaMatrix Jazz Blood Glucose Test Strips was established in k103544 to support a shelf life of 21 months and open vial stability of 180 days when stored at 46ºF to 86ºF and relative humidity of 10-90%.

Control Solution:
Stability of the AgaMatrix Control Solutions Level 2 and Level 4 was established in k103544) to support the labeling storage claim of 90 days when stored at 36ºF to 86ºF.

d. Detection limit:

See linearity study in Section M.1.b above.

e. Analytical specificity:

An interference study was performed using three venous whole blood samples (with glucose concentrations 75, 120, 300 mg/dL) that were spiked with potentially interfering endogenous and exogenous substances at high levels. Each sample was measured on ten meters using three strip lots for a total of 30 replicates per sample. The effect of the potential interferent was assessed by calculating the bias difference in glucose readings between the test sample with high interferent concentration and the control sample with no interferent. The sponsor claims no significant interference (≤ 10% difference) for the substances and concentrations 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	Lactose	10
Ascorbic acid	3.0	L-DOPA	4
Bilirubin, conjugated	29	Maltose	278
Bilirubin, Free	20	Mannitol	53
Caffeine	6	Methyl-DOPA	1.5
Ceftriaxone	97	PAM iodide	80
Cholesterol	600	Pralidoxime	52
Creatinine	5	Salicylate	60
Dopamine	0.09	Sorbitol	600
Fructose	18	Sucrose	20
Galactose	120	Tolazamide	5
Gentisic acid	1.8	Tolbutamide	64
Glutathione	92	Triglyceride	3300
Hemoglobin	200	Uric acid	23.5
Heparin	1.9	Xylitol	60.9
Ibuprofen	50	Xylose	120
Icodextrin	620	α-Lipoic acid	2

The sponsor has included the following limitation in the labeling: If you are taking Vitamin C (ascorbic acid) >3 mg/dL you may get inaccurate results with this system.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy, results from the AgaMatrix Jazz Wireless 2 System were compared to a reference method, YSI Model 2300 Glucose Analyzer using 124 capillary blood samples with glucose concentrations ranging from 35.9 to 539.8 mg/dL. To obtain extreme glucose concentrations, samples with glucose less than 50 mg/dL were obtained by allowing samples to glycolyze and glucose concentrations greater than 400 mg/dL were obtained by spiking. The meter results relative to YSI are summarized in the tables below:

Summary of system accuracy results for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
19/32 (59.4%)	29/32 (90.6%)	31/32 (96.9%)

Summary of system accuracy results for glucose concentrations ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
63/92 (68.5%)	87/92 (94.6%)	91/92 (98.9%)	92/92 (100.0%)

Linear Regression Analysis: $y = 1.05x - 7.49$; $r = 1.00$

b. Matrix comparison:

Not applicable. Only capillary whole blood samples are an acceptable matrix.

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 AgaMatrix Jazz Wireless 2 System in the hands of the intended users a lay user study was conducted with 100 lay users, given only the instructions and training materials routinely provided with the system. The range of samples tested was 42.8-396.0 mg/dL according to the reference measurement (YSI). The blood glucose results obtained from the finger by the subjects using the meter were compared to the YSI 2300 reference results. The results from this study are summarized below:

Summary of system accuracy user finger results for glucose concentrations <75mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
4/4 (100.0%)	4/4 (100.0%)	4/4 (100.0%)

Summary of system accuracy user finger results for glucose concentrations ≥75mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
48/96 (50.0%)	77/96 (80.2%)	91/96 (94.8%)	95/96 (99.0%)

Linear Regression Analysis: $y = 1.04 + 2.10$; $R^2 = 0.99$

The lay users also completed a questionnaire in order to evaluate the system's user guides and messages displayed on the meter for clarity and usefulness.

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Expected blood glucose levels for people without diabetes: Fasting <100 mg/dL, two hours after meals <140 mg/dL.

Reference citation: American Diabetes Association: Standard of Medical Care in Diabetes 2016, Diabetes Care, 2016:39 (Suppl 1): S13-S22.

N. Instrument Name:

AgaMatrix Jazz Wireless 2 Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and requires a sample volume of 0.5 µl.

   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 ___X_____ or No _____

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 strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The meter is automatically coded. No calibration is required by the user.

6. Quality Control:

   Two levels of aqueous glucose control solutions, the AgaMatrix Control Solutions (Level 2 and Level 4) are available (sold separately) for use with this system. No control solution is provided with the AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System. Instructions on how to order the control solutions are included in the owner's guide. The meter has the ability to distinguish between control solution and a blood sample to prevent control results from being stored in the internal memory as patient results. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label.

The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Altitude Study:
   The effect of altitude on meter results was evaluated by testing three venous blood samples with glucose concentrations of 50, 200 and 450 mg/dL at 10,000 feet above sea level and at sea level. Results obtained on the subject device were compared to those obtained with the YSI 2300 reference method. The results support the claim in the labeling that altitude up to 10,000 feet do not significantly affect device performance.

2. Hematocrit Study:
   The system was tested with venous whole blood samples at three glucose concentrations (40, 125, and 350 mg/dL) and nine hematocrit levels (20, 25, 30, 35, 40, 45, 50, 55, 60%). Each sample was measured with ten meters and three test strip lots for a total of 30 replicates, and with the YSI 2300 reference method. Results from the study support the claimed hematocrit range of 20 – 60%.

3. Temperature and Humidity Study:
   Operating temperature and humidity studies were performed using venous whole blood samples to evaluate temperatures ranging from 10 ºC to 40 ºC and relative humidity from 10% to 90%. Testing was conducted at target glucose concentrations of 50, 200, and 450 mg/dL. Meter results were compared to YSI reference analyzer. Five temperature and humidity combinations were tested: low temperature/low humidity, low temperature/high humidity, high temperature/low humidity, high temperature/high humidity and medium temperature/medium humidity (control condition). Each sample was tested with 30 replicates. Results obtained were compared to those obtained with the YSI 2300 reference method. The results support the claims in the labeling that the device can be used in conditions of 50°F to 104°F (10°C to 40°C) with relative humidity of 10 to 90%.

4. Infection Control Studies:
   The device system is intended for single-patient use only. Disinfection efficacy testing was performed on the external Jazz™ Wireless 2 meter materials by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, PDI Super Sani-Cloth Germicidal Disposable Wipes (EPA number 9480-4). Robustness testing was also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 260 cleaning and 260 disinfection cycles, for a total of 520 wipes (260 cleaning wipes plus 260 disinfecting wipes), designed to simulate 5 years of use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

5. Sample Volume Study:
   A sample volume study was performed to verify the claimed minimum sample volume requirement. One lot of test strips was tested at three glucose intervals, using ten blood

glucose meters. Blood samples at glucose levels 50-65, 100-120, and 200-250 mg/dL were tested on the meter and compared to YSI values at five sample volumes of 1.0, 0.6, 0.5, 0.4 and 0.3µL. Protocols and acceptance criteria were provided and found to be acceptable. The results support the claimed minimal sample volume of 0.5µL.

6. Readability Assessment:
   The Flesch-Kincaid Grade level assessment was conducted on the Owner's Guide, Meter Pairing & Syncing Guide, and Test Strip Insert. No readability assessment was above grade level 8.

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

8. Customer Support is available 24 hours a day, 7 days per week. The toll free phone number is 1‑866-906-4197.

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.