DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

AGAMATRIX, INC.
DAVID OLSEN
VP QUALITY & REGULATORY AFFAIRS
7C RAYMOND AVENUE
SALEM NH 03079

April 21, 2016

Re: K152365
Trade/Device Name: Agamatrix Jazz Wireless 2 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: April 12, 2016
Received: April 14, 2016

Dear Mr. Olsen:

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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152365

Device Name
AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System

Indications for Use *(Describe)*

AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System:
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 blood glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

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

A. 510(k) Number:

K152365

B. Applicant:

AgaMatrix, Inc.
7C Raymond Avenue
Salem, NH 03079
606 328 6064

Contact Person: David Olsen
Date Summary Prepared: April 8, 2016

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose Oxidase (GO)

E. Purpose for Submission:

New Device

F. Proprietary and Established Names:

AgaMatrix Jazz™ Wireless 2 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section

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):

Blood Glucose Monitoring

2. Indication(s) for use:

AgaMatrix Jazz™ Wireless 2 Blood Glucose Monitoring System:
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.

AgaMatrix Jazz™ Blood Glucose Test Strips:
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 fingertip.

3. Special conditions for use statement(s):

- It is intended to be used by a single person and should not be shared.
- For over-the-counter use.
- It is not intended to be used for testing neonatal blood samples or the diagnosis or screening of diabetes.

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 AgaMatrix Jazz™ Wireless 2 Blood Glucose Meter and the AgaMatrix Jazz™ Blood Glucose Test Strips. The apply blood symbol is displayed for the user to apply blood to the test strip until the meter begins the test. When enough blood has been applied to the strip electrodes the meter detects trigger current from the test strip initiating the test countdown. When the countdown is complete a test result is displayed on the meter screen. The unit of measure displayed on the meter screen is fixed in mg/dL and cannot be modified by the user.

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

- 1 AgaMatrix Jazz™ Wireless 2 Glucose Meter
- 1 Owner's Guide
- 1 Carry Case
- 1 AgaMatrix Lancing Device
- 10 AgaMatrix Lancets
- AgaMatrix Jazz™ Blood Glucose Test Strips
- 1 Meter Pairing & Syncing Guide

The following items are compatible with the AgaMatrix Jazz™ Wireless 2 Glucose Monitoring System and are available separately:

- AgaMatrix Glucose Control Solutions (cleared in K103544)
- AgaMatrix Diabetes Manager Mobile Application (cleared in K132821)

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/Differences		
Item	Predicate Device iBGStar Blood Glucose Monitoring System (K103544)	Candidate Device AgaMatrix Jazz™ Wireless 2 Blood Glucose Monitoring System
Intended Use/Indications for Use	The iBGStar™ Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. It is intended to be used by a single patient and should not be used for testing multiple patients. The iBGStar™ 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 iBGstar Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.	Same with the following differences: Finger tip sampling only
Detection method	Dynamic Electrochemistry	Same
Enzyme	Glucose Oxidase	Same
Calibration Coding	Non-Coding	Same
Sample Type	Capillary whole blood	Capillary whole blood

Sample sites	finger, forearm, upper arm or palms (base of thumb)	Finger tip
Sample volume	0.5 µL	Same
Average test time	5 seconds	Same
Test range	20 - 600 mg/dL	Same
Operating Temperature	50° - 104°F	Same
Measurment Range	20 to 600 mg/dL	Same
Calibration	Plasma Equivalent	Same
Control levels	Two Levels	Same
Operating Humidity	Up to 90%,	10% - 90%
Hematocrit range	20 - 60%	Same
Altitude Study	Up to 10,000 feet	Same
Connectivity	Meter utilizes a 30-pin dock connecter to directly connect to iPhone /iPod touch or Apple Lightning Adapters.	Meter is Bluetooth capability for communication with appropriate iOS or Android software application.
Meter size	L- 56 mm, W-24 mm, H-10mm	L-65 mm, W-30 mm, H-10 mm

Weight	8.5g	18g
Number of results stored	300	300
Power Source	A polymer lithium-ion rechargeable battery	(2) replaceable CR2032 3 volt, lithium batteries
Alternative Site Testing	Yes (Palm and Forearm)	No (Fingertip sampling only)

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 Electrical Equipment-Part1-2: General requirements for Basic Safety and Essential Performance-Collateral Standard: Electromagnetic Compatibility-Requirements and Tests-Edition 3.0:2007

L. Test Principle:

The AgaMatrix Jazz™ Blood Glucose Test Strips contain 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:

i. 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 below:

Glucose Concentration, (mg/dL)	Strip Lot	n	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	118	34.8	2.4	6.9
	2	119	31.3	1.6	5.3
	3	119	30.6	2.6	8.5
	Combined			2.9	9.0
51-110	1	120	100.8	3.2	3.2
	2	120	96.4	3.9	4.0
	3	120	96.9	4.0	4.1
	Combined			4.2	4.3
111-150	1	120	132.9	2.6	2.0
	2	120	129.3	4.2	3.3

Glucose Concentration, (mg/dL)	Strip Lot	n	Mean (mg/dL)	SD (mg/dL)	CV (%)
	3	120	128.5	3.9	3.0
	Combined			4.1	3.2
151-250	1	120	220.1	6.5	2.9
	2	120	221.1	7.7	3.5
	3	120	229.5	5.0	2.2
	Combined			7.7	3.5
251-400	1	120	388.0	9.9	2.5
	2	120	379.9	16.3	4.3
	3	120	380.4	17.3	4.6
	Combined			15.3	4.0

ii. Intermediate precision of the Kronos BGMS was established by evaluating three glucose control solutions, with multiple meters (10 meters) over multiple days (10 days) using three different operators and three lots of test strips. The results are summarized below:

Test Strip Lot 1			
Control Solution	**Mean, mg/dL**	**SD, mg/dL**	**% CV**
Level 1	57.1	1.6	2.8
Level 2	134.0	3.4	2.6
Level 4	343.5	8.5	2.5

Test Strip Lot 2			
Control Solution	**Mean, mg/dL**	**SD, mg/dL**	**% CV**
Level 1	57.8	2.2	3.7
Level 2	137.9	2.9	2.1
Level 4	345.5	8.8	2.6

Test Strip Lot 3			
Control Solution	**Mean, mg/dL**	**SD, mg/dL**	**% CV**
Level 1	57.1	1.8	3.1
Level 2	134.3	3.1	2.3
Level 4	342.5	7.4	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. Study design and analysis followed CLSI EP6-A. 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):

<u>Traceability</u>

The device is factory calibrated. Further calibration by the user is not necessary for operation. The calibration is traceable to NIST SRM 917c.

Stability

Test strip stability:
The test strips remain unchanged compared to the test strips of the predicate device (iBGStar BGMS K103544). The test strips have a shelf life of 21 months when stored unopened at 8 ºC to 30 ºC, and are stable for 180 days after first opening when stored within the recommended storage conditions.

Control Solution:
The control solutions compatible for use with the current device (AgaMatrix Control Solution Level 2 and Level 4 were previously cleared and stability and value assignment was established in K103544).

d. Detection limit:

The reportable range for the AgaMatrix Jazz™ Wireless 2 Blood Glucose Monitoring System is 20 to 600 mg/dL.

e. Analytical specificity:

i. To assess potential interference, three venous whole blood samples (with glucose concentrations 75, 120, 300 mg/dL) were spiked with potentially interfering substances at high (toxic / pathological) levels. Study design and analysis followed CLSI EP7-A2 guidance. 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 average difference in glucose readings between the test sample with high interferent concentration and the control sample with low/no interferent. Significant interference was defined as a bias in readings between the tested and control sample of > ± 10 mg/dL for glucose concentrations < 100 mg/dL or a bias of > ± 10% for glucose concentrations > 100 mg/dL.

Among the 35 interferents tested, only ascorbic acid exhibited potential interference. Therefore, a dose response study was performed and the upper limit for no significant interference was estimated at 2.9 mg/dL. The following limitation has been added to the labeling: "If you are taking Vitamin C (ascorbic acid) at large doses you may get inaccurate results with this system."

A summary of the concentrations of the potential interfering substances tested at which no significant interference is observed is summarized in the table below:

Interferent	Highest concentration tested with no significant interference (mg/dL)	Interferent	Highest concentration tested with no significant interference (mg/dL)
Acetaminophen	20	Lactose	10
Ascorbic acid	3	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 chloride	52
Creatinine	5	Salicylate	60
Dopamine	0.09	Sorbitol	600
EDTA	0.1	Sucrose	20
Fructose	18	Tolazamide	5
Galactose	120	Tolbutamide	64
Gentisic acid	1.8	Triglyceride	3300
Glutathione	92	Uric acid	23.5
Hemoglobin	200	Xylitol	60.9
Heparin	1.9	Xylose	120
Ibuprofen	50	α-Lipoic acid	2
Icodextrin	620		

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The AgaMatrix Jazz™ Wireless 2 Blood Glucose Monitoring System accuracy was evaluated using 124 whole blood samples (117 obtained by fresh capillary fingerstick and 7 altered blood samples) ranging in concentration from 35.9 -539.8 mg/dL. Three lots of test strips were tested in the study. Blood glucose results obtained with the meter to the plasma glucose results obtained using the YSI Model 2300 Glucose Analyzer. The study concluded that the AgaMatrix Jazz™ Wireless 2 Blood Glucose Monitoring System demonstrates acceptable system accuracy. The results of the study are summarized below:

For glucose concentrations < 75 mg/dL

Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	19/32 (59.4%)	29/32 (90.6%)	31/32 (96.9%)
2	21/32 (65.6%)	30/32 (93.8%)	32/32 (100.0%)
3	16/32 (50.0%)	30/32 (93.8%)	32/32 (100.0%)
Combined	56/96 (58.3%)	89/96 (92.7%)	95/96 (99.0%)

For glucose concentrations ≥ 75 mg/dL

Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	63/92 (68.5%)	87/92 (94.6%)	91/92 (98.9%)	92/92 (100.0%)
2	57/92 (62.0%)	81/92 (88.0%)	88/92 (95.7%)	91/92 (98.9%)
3	47/92 (51.1%)	81/92 (88.0%)	90/92 (97.8%)	91/92 (98.9%)
Combined	167/276 (60.5%)	249/276 (90.2%)	269/276 (97.5%)	274/276 (99.3%)

Linear Regression Analysis

Lot	Slope	Intercept (mg/dL)	r	n	Range of Reference Values (mg/dL)
1	1.05	-7.49	1.00	124	35.9 – 539.8
2	1.02	-3.21	0.99	124	
3	1.02	-7.74	0.99	124	
Combined	1.02	-4.03	0.99	372	

b. Matrix comparison:

Not applicable. Capillary whole blood from the finger is the only indicated 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:

A lay user study was conducted to assess the accuracy and usability of the blood glucose meter in the hands of the intended user. The study was conducted using 100 lay users with Type 1 or Type 2 diabetes, using one lot of test strips, to evaluate that the intended users are able to obtain accurate glucose measured values when operating the blood-glucose monitoring system, given only the instructions and training materials routinely provided with the system. The blood glucose results obtained from the finger by the subjects were compared to the YSI 2300 reference results.

The results from this study indicate that the lay user can operate the AgaMatrix Jazz™ Wireless 2 Blood Glucose Monitoring System and obtain accurate results from the finger given only the instructional materials routinely provided to new users. In summary, all AgaMatrix Jazz™ Wireless 2 BGMS performance criteria were met with the following results:

For glucose concentrations < 75 mg/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%)

For glucose concentrations ≥ 75 mg/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

Slope	Intercept (mg/dL)	r	n	Range of Reference Values (mg/dL)
1.04	2.10	0.99	100	42.8-396.0

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. Classification and diagnosis of diabetes. Sec. 2. In Standards 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 must be replaced with a new strip for additional readings.

   Does the applicant's device transmit data to a computer, web server, 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. SpecimenSamplingandHandling:

   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. QualityControl:

   Two levels of aqueous glucose control solutions 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 three venous blood samples with glucose concentrations of 50, 200 and 450 mg/dL at 10,000 feet altitude and sea level. Results obtained were compared to those obtained with the YSI 2300 reference method. The results demonstrate acceptable bias relative to the reference method to support the claim in the labeling that altitudes 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 claimed hematocrit range of 20 – 60%.

3. Temperature and Humidity Study

   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 10 ºC to 40°C with relative humidity of 10 to 90%.

4. Infection Control Studies:

   Disinfection testing was performed on the materials that make up the surfaces of the AgaMatrix Jazz™ Wireless 2 Meter and the lancing device by an outside lab. The results with PDI® Super Sani-Cloth® Germicidal Disposable Wipes with EPA number 9480-4 demonstrated complete inactivation of live virus.

Robustness testing was performed with the AgaMatrix Jazz™ Wireless 2 Meter and lancing device using the PDI® Super Sani-Cloth® Germicidal Disposable Wipes with EPA number

9480-4. The results demonstrated there was no change in performance or material of the tested devices at the conclusion of the disinfection and robustness testing which consisted of 260 cleaning/disinfection cycles designed to simulate 5 years of use.

5. Sample Volume Study

   A sample volume study was performed to verify the claimed 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, 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 0.3 µL. The results support the claimed minimal sample volume of 0.5 µL.

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.

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.