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

A. 510(k) Number:

k140210

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose, venous, and arterial.

D. Type of Test:

Quantitative Amperometric assay (FAD-Glucose Dehydrogenase)

E. Applicant:

BIONIME Corporation

F. Proprietary and Established Names:

Rightest Blood Glucose Monitoring System GM720
Rightest Professional Blood Glucose Monitoring System GM720

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, System, Test, Blood Glucose, Over The Counter
   LFR, Glucose Dehydrogenase, Glucose or CGA, Glucose Oxidase, Glucose

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for use:

   The **Rightest Blood Glucose Monitoring System GM720** is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM720 is intended to be used by a single person and should not be shared.

   The Rightest Blood Glucose Monitoring System GM720 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 Rightest Blood Glucose Monitoring System GM720 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady- state times (when glucose is not changing rapidly).

   The Rightest Blood Glucose Test Strips GS720 are for use with the Rightest Blood Glucose Meter GM720 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

   The **Rightest Professional Blood Glucose Monitoring System GM720** is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm and in venous and arterial whole blood. The Rightest Professional Blood Glucose Monitoring System GM720 is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with auto-disabling, single-use lancing devices. The Rightest Professional Blood Glucose Monitoring System GM720 should not be used for the diagnosis of, or screening for diabetes, nor for testing neonate blood samples. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

   The Rightest Professional Blood Glucose Test Strips GS720 are for use with the Rightest Professional Blood Glucose Meter GM720 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm and in venous and arterial whole blood samples.

3. Special conditions for use statement(s):

The Rightest® Blood Glucose Monitoring System GM720:

- Is intended for self-testing and is for single-patient use only
- It should not be used to diagnose diabetes mellitus.
- AST should not be used to calibrate continuous glucose monitors (CGMs)
- AST should not be used for insulin dose calculations
- For over-the-counter use
- Is not for use on critically ill patients
- For in vitro diagnostic use only
- Not for Neonate use
- Not for use in patients in shock, dehydrated patients or hyper-osmolar patients.

The Rightest Professional Blood Glucose Monitoring System GM720:

- It should not be used to diagnose diabetes mellitus.
- AST should not be used to calibrate continuous glucose monitors (CGMs)
- AST should not be used for insulin dose calculations
- Has not been evaluated in the critically ill.
- For in vitro diagnostic use only
- Not for testing neonate cord blood samples
- Should be used with single-use, auto-disabling lancing devices.
- Not for use in patients in shock, dehydrated patients or hyper-osmolar patients.

4. Special instrument requirements:

Rightest® Blood Glucose Meter GM720
Rightest® Professional Blood Glucose Meter GM720

I. Device Description:

The Rightest Blood Glucose Monitoring System GM720 (single patient use) consists of the following components: Rightest Blood Glucose Meter GM720, Rightest Blood Glucose Test Strip GS720, Rightest Control Solution GC700. The Rightest Professional Blood Glucose Monitoring System GM720 (multiple patient use) consists of the following components: Rightest Professional Blood Glucose Meter GM720, Rightest Professional Blood Glucose Test Strip GS720, and Rightest Professional Control Solution GC700. Both The Rightest Blood Glucose Monitoring System GM720 and the Rightest Professional Blood Glucose Monitoring System GM720 are autocoding meters. A minimum of 0.75 microliter of blood is placed on a disposable test strip coated with FAD-glucose Dehydrogenase (FAD-GDH). The Owner's booklet and carrying case are provided in the kit. The control solutions for this Blood Glucose Monitoring System were previously cleared as Rightest Control Solutions Level 1, 2 and 4 in k110737. Level 1 (40-50 mg/dL), Level 2 (120- 150 mg/dL), and Level 4 (330-360 mg/dL) control solutions are sold separately and are not included with the meter.

The differences between the single-patient use Rightest Blood Glucose Monitoring System GM720 and the multiple patient use Rightest Professional Blood Glucose Monitoring System GM720 are the labeling, which includes the names of the system components, and disinfection instructions for using the device on single-patients versus in multiple patient use settings.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACCU-CHEK Performa Blood Glucose Monitoring System

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

   k070585

3. Comparison with predicate:

	Similarities of the Blood Glucose System		
Item	Predicate Device ACCU-CHEK Performa Blood Glucose Monitoring System (k070585)	Candidate Device Rightest Blood Glucose Monitoring System GM720	Candidate Device Rightest Professional Blood Glucose Monitoring System GM720
Intended Use/Indications for Use	It is intended to be used for quantitative measurement of glucose as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same	Same
Measurement Technology	Dehydrogenase Electrochemical Sensor	Same	Same

Enzyme	FAD-glucose Dehydrogenase (FAD-GDH) 12.1%	Same	Same
Sample sites	Fingertip, forearm, palm	Same	Same

	Differences of the Blood Glucose System		
Item	Predicate Device ACCU-CHEK Performa Blood Glucose Monitoring System (k070585)	Candidate Device Rightest Blood Glucose Monitoring System GM720	Candidate Device Rightest Professional Blood Glucose Monitoring System GM720
Memory	500 blood glucose test results with date and time	1000 blood glucose test results with date and time	1000 blood glucose test results with date and time
Hematocrit range	10-70%	20-65%	20-65%
Test range	10 - 600 mg/dL	20 – 600 mg/dL	20 – 600 mg/dL
Calibration Coding	Code Key	Auto coding	Auto coding

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

- ISO 15197:2003, In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- ISO 14971:2007, Medical devices – Application of risk management to medical devices.
- IEC 60601-1-2, Medical electrical equipment Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility- Requirements and tests.
- IEC 60601-1, Medical Electrical Equipment-Part 1: General Requirements for Safety.
- IEC 61000-4-2 Electromagnetic compatibility (EMC)-Part 4-2: Testing and measurement techniques-Electrostatic discharge immunity test.: 2008
- IEC 61000-4-3: Electromagnetic compatibility (EMC) – Part 4-3 2006+A1:2007: Testing and measurement techniques-Radiated, radio-frequency, electromagnetic field immunity test.

- IEC 61000-4-8, Electromagnetic compatibility (EMC)-Part 4-8: Testing and measurement techniques-Power frequency magnetic field immunity test.
- CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline.

L. Test Principle:

The Rightest Blood Glucose Monitoring System, Model GM720 uses electrochemical methodologies. The system quantitatively measures blood glucose levels using an amperometric method. The system employs flavin adenine dinucleotide-glucose dehydrogenase (GDH-FAD) enzyme chemistry. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

M. Performance Characteristics (if/when applicable):

All performance characteristics were conducted on Rightest Blood Glucose Meter GM720 using the Rightest Blood Glucose Test Strip GS720. Testing performed on the Rightest Blood Glucose Meter GM720 and the Rightest Blood Glucose Test Strip GS720 to characterize performance of both the Rightest Blood Glucose Monitoring System GM720 and the Rightest Professional Blood Glucose Monitoring System GM720 is adequate since both meters and the respective test strips are identical.

1. Analytical performance:

a. Precision/Reproducibility

Within-run (Repeatability)
Venous blood from one donor was adjusted with glucose to five glucose levels (30-50, 51-110, 111-150, 151-250, 251-400) across the claimed range and tested on three lots of strips on 30 meters (10 meters per test strip lot). Ten replicates were tested per meter, test strip lot and glucose concentration. Results are summarized below:

Glucose Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	100	1	34.8	1.3	3.7
		2	34.3	1.2	3.4
		3	36.5	1.2	3.2
51-110	100	1	92.6	2.3	2.5
		2	87.0	2.2	2.5
		3	88.2	2.0	2.3
111-150	100	1	128.1	2.6	2.0
		2	127.9	3.1	2.5
		3	128.5	2.3	1.8
151-250	100	1	207.9	3.9	1.9
		2	205.2	3.8	1.9
		3	207.8	3.9	1.9

251-400	100	1	360.7	5.4	1.5
		2	360.2	7.1	2.0
		3	358.4	4.8	1.4

Intermediate Precision

Intermediate precision was evaluated using three lots of test strips and ten meters. Glucose control solutions in three concentration ranges were used (low range: 46.5~51.5 mg/dL, mid-range: 95~105 mg/dL, and high range: 285~315 mg/dL). Each control solution was measured 10 times, on three test strip lots over 10 days, so that 100 individual measurements were generated (300 measurements per glucose level). Results are summarized below:

Control Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
Low Range 46.5~51.5	100	1	49.7	1.5	2.9
		2	54.3	1.5	2.7
		3	56.2	1.5	2.6
Normal range 95~105	100	1	101.9	2.1	2.0
		2	104.7	2.0	1.9
		3	108.6	2.2	2.0
High range 285~315	100	1	285.1	4.4	1.5
		2	268.9	6.2	2.3
		3	271.9	5.8	2.1

b. Linearity/assay reportable range:

Linearity was evaluated using 15 venous blood glucose samples to cover the 20-600 mg/dL measuring range. Glucose concentrations according to the reference method were as follows: 0, 17.7, 23.7, 54.1, 116.5, 149.5, 215.0, 260.5, 318.5, 352.5, 410.0, 476.5, 506.5, 542.5, 617.5 mg/dL. Each glucose level was measured in triplicate on 3 lots. Linear regression analysis for each test strip lot compared to the YSI resulted in:

$y = 1.0311x – 5.3228$; $R^2 = 0.9993$ for Test Strip Lot 1
$y = 1.0213x – 6.7709$; $R^2 = 0.9986$ for Test Strip Lot 2
$y = 1.0203x – 4.694$; $R^2 = 0.9983$ for Test Strip Lot 3
$y = 1.0226x – 5.023$; $R^2 = 0.9982$ for the lots combined

The results of the study support the sponsor's claimed glucose measuring range of 20 to 600 mg/dL for this device. Data from bench studies and software verification studies were provided to demonstrate that if a sample is less than 20 mg/dL glucose, the result is flagged by the meter as LO and if a sample result exceeds 600 mg/dL glucose, the result is flagged by the meter as HI.

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

1. Traceability

The system is traceable to the NIST SRM 917b, dry D-glucose, reference material.

2. Stability

Stability testing protocols and acceptance criteria for Rightest Blood Glucose Test Strips GS720 were previously reviewed in k110737. The manufacturer claims shelf life stability of 18 months and an open-vial stability of 4 months at the recommended storage temperatures of 39°F-86°F with 10-90% relative humidity.

Control Solution Value Assignment and Stability:

Value assignment was established for the Rightest Control Solutions Level 1, 2 and 4 in k110737.

Stability testing protocols and acceptance criteria were previously reviewed and found to be acceptable to support the shelf life stability claim of 16 months and an open-vial stability claim of 3 months when stored at the recommended storage temperatures of 36°F to 86°F.

d. Detection limit:

See linearity study in Section M1b above.

e. Analytical specificity:

To assess potential interference the sponsor used three test strip lots to evaluate two glucose concentration intervals (60-100 and 150-300 mg/dL) in order to analyze 19 substances tested at a therapeutic and a toxic level. . Glucose values measured with Rightest Blood Glucose Monitoring System at test conditions were compared with values measured at control condition (without interferent). Results are presented in the table below:

Potential Interfering Substance	**Concentration at which no significant interference is observed (mg/dL)**
Acetaminophen	20
Ascorbic acid	3
Bilirubin	40
Cholesterol	700
Creatinine	10
Dopamine	1.25
Galactose	60

Icodextrin	500
Ibuprofen	50
Lactose	50
L-Dopa	3
Maltose	200
Methyldopa	1.5
Salicylic acid	20
Teracycline	1.5
Tolbutamide	100
Triglycerides	3000
Uric acid	16
Xylose	18

Based on observed results, the sponsor has the following limitations in the labeling:

Xylose ≧ 10 mg/dL, Uric acid ≧ 16 mg/dL, Ascorbic acid ≧ 3 mg/dL, and Dopamine HCl ≧ 1.25 mg/dL may result in inaccurate test results.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device

Healthcare professionals tested 121 capillary samples ranging in glucose concentration from 43.5 – 465mg/dL, using 2 meters and 3 lots of test strips on fingertip, palm, and the forearm. Reference values were obtained on an Olympus AU 640 analyzer.. Six samples < 50 mg/dL and 6 samples > 400 mg/dL were altered.

The meter results relative to Olympus AU 640 are summarized in the tables below:

Fingertip:

Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
19	17/19 (89.5%)	19/19 (100%)	19/19 (100%)

Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
102	71/102 (69.6%)	92/102 (90.2%)	102/102 (100%)	102/102 (100.0%)

Liner Regression:

Y=1.010X – 3.41; r=0.995

Palm:

Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
19	17/19 (100%)	19/19 (100%)	19/19 (100%)

Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
102	70/102 (68.6%)	89/102 (87.3%)	101/102 (99.0%)	102/102 (100%)

Liner Regression:

Y=0.999X +1.08; r=0.996

Forearm:

Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
19	19/19 (100%)	19/19 (100%)	19/19 (100%)

Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
102	65/102 (63.7%)	85/102 (83.3%)	100/102 (98.0%)	102/102 (100%)

Liner Regression:

Y=1.009X – 2.62; r=0.996

b. Matrix comparison:

Venous blood: A total of 121 Lithium Heparin anticoagulated venous blood samples with glucose values ranging from 43.5 – 462.5 mg/dL (Olympus AU 640) were evaluated in this study. The meter results relative to Olympus AU 640 are summarized in the tables below:

Glucose < 75 mg/dL

Number of test results	Within ± 5 mg	Within ± 10 mg	Within ± 15 mg
20	20/20 (100%)	20/20 (100%)	20/20 (100%)

Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
101	76/101 (75.2%)	98/101 (97.0%)	101/101 (100%)	101/101 (100%)

Linear regression :

Y=0.972X+3.88; r=0.997

Arterial Blood : 106 arterial blood samples measured with Rightest Blood Glucose Monitoring System GM720 were compared with Olympus AU400. A total of 106 Lithium Heparin anti-coagulated arterial blood samples with glucose values ranging from 32.0 – 518.0 mg/dL (Olympus AU 400) were evaluated in this study. The meter results relative to Olympus AU 400 are summarized in the tables below:

Glucose < 75 mg/dL

Number of test results	Within ± 5 mg	Within ± 10 mg	Within ± 15 mg
4	3/4 (75%)	4/4 (100%)	4/4 (100%)

Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
102	73/102 (71.6%)	97/102 (95.1%)	102/102 (100%)	102/102 (100%)

Linear regression :

Y=1.014X-0.87; r=0.993

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

Fingerstick, palm, and forearm: The user performance study was performed to compare the lay user self-test results and the YSI method. Study was performed at multiple clinical sites with 165 subjects self-testing using the fingertip and palm and 164 subjects self-testing for the forearm. The study participants were provided with the User's Manual in English, and performed fingerstick, palm, and forearm tests on their own. A technician collected capillary blood from each participant for measurement on YSI. The range of glucose values for the finger stick samples was 54 -333 mg/dL measured by YSI. Three test strip lots were tested in the study.

Result Summary:

Fingertip:

Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7	6/7 (85.7%)	7/7 (100%)	7/7 (100%)

Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
156	86/156 (55.1%)	133/156 (85.3%)	150/156 (96.2%)	156/156 (100.0%)

Liner Regression:

Y=0.98X +0.87; r=0.99

Palm:

Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7	7/7 (100%)	7/7 (100%)	7/7 (100%)

Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
156	68/156 (43.6%)	126/156 (80.8%)	150/156 (96.2%)	153/156 (98.1%)

Liner Regression:

Y=1.00X + 0.66; r=0.99

Forearm:

Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7	7/7 (100%)	7/7 (100%)	7/7 (100%)

Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
153	76/153 (49.7%)	124/153 (81.0%)	145/153 (94.8%)	150/153 (98.0%)

Liner Regression:

Y=0.99X + 1.12; r=0.99

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

Expected glucose values without diabetes

Status	Range (mg/dL)
Fasting	<100 mg/dL
Two Hours after meals	<140 mg/dL

Reference:
American Diabetes Association: Standard of Medical Care in Diabetes 2011, Diabetes Care,Vol.34, supplement 1, S11-S61, January 2014.

N. Instrument Name:

Rightest Blood Glucose Meter GM720

Rightest Professional Blood Glucose Meter GM720

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 0.75 μL.

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

Yes _____ or No ___X_____

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 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 and palm or forearm. The whole blood sample is applied directly to the test strip by capillary action. The professional version of the meter is validated for venous, and arterial blood.

5. Calibration:

   There is no calibration required for the blood glucose meter by the user. The meter is automatically coded.

6. Quality Control:

   Glucose control solutions at 3 different concentrations can be run with this device. The meter automatically distinguishes control solution from blood and marks control solution tests with a check mark and excludes them from average calculations. 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 bottle label and on the bottom of the test strip box. 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. **Sample volume study:**
   Rightest Blood Glucose Monitoring System GM720 was tested with venous blood at three glucose concentration intervals (40-60, 80-120, and 300-330 mg/dL) and nine specimen volumes. For each glucose interval, the specimen volumes were adjusted to 0.60, 0.65, 0.70, 0.75, 0.80, 1.00, 1.25, 2.00, and 3.00μL. Each sample was measured in three replicates for each of three test strip lots and same sample was also measured by YSI. The bias for the three replicates in each test strip lot was calculated. Results support the claimed minimum sample volume of .75 μL.

2. **Altitude Study:**
To evaluate the effects of altitude, 3 test strip lots were tested on 3 meters using three whole blood samples with glucose concentrations of 50-75, 80-120, and 270-330 mg/dL. The samples were tested at 3281 ft, 6562 ft and 10,000 ft above sea level and at sea level (0 feet) as a control. Results obtained were compared with those obtained with the reference method (YSI). The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,000 ft have no significant effect on blood glucose measurements from the Rightest GM720 glucose meter.

3. **Hematocrit Study:**

The Rightest Blood Glucose Monitoring System GM720 was tested with venous blood at six glucose concentrations (20-50, 60-80, 135-165, 180-220, 270-330 and 360-440 mg/dL). For each glucose concentration interval, the hematocrit levels were adjusted to 10, 20, 25, 30, 40, 55, 60, 65 and 70%. Each sample was measured in replicates of five on three test strip lots. Results were compared to YSI. The % bias relative to YSI demonstrated adequate performance to support the claimed hematocrit range of 20 – 65%.

4. **Test System operating conditions:**

Temperature and humidity operating conditions were evaluated for temperatures ranging from 42.8^{o}F-111.2^{o}F and relative humidity from 10% to 90% including extreme combinations of temperature and humidity, e.g. lowest humidity with lowest and highest temperature and highest humidity with lowest and highest temperature. Protocol and acceptance criteria were provided and found to be acceptable. The results supported the Sponsor's claimed operating temperature from 42.8^{o}F-111.2^{o}F and relative humidity range from 10% to 90%.

5. **Readability Assessment:**
The readability of the labeling (user guide, quick reference guide and test strip insert) using a Flesch-Kincaid analysis were found to be written at the 8th grade level.

During the lay user study described above in Section M.3.c, the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall the users indicated that they could successfully perform the test and that the user manual was written clearly.

6. **EMC Testing:**

The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed using IEC 60601-1-2; Medical electrical equipment- Part l-2: General requirements for safety - Collateral standard : Electromagnetic compatibility - Requirements and tests.

7. Infection Control Studies:

The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of Hepatitis B Surface Antigen (HBsAg) with the chosen disinfectant, Discide® ultra disinfecting towelettes, EPA Reg. # 10492-4. Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 12000 cleanings and 12000 disinfection steps with the 24000 wipes. The robustness studies were designed to simulate 3 years of multiple-patient use. 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.