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

A. 510(k) Number:

k133260

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, amperometric assay using Glucose Oxidase technology

E. Applicant:

Tianjin Empecs Medical Device Co., Ltd.

F. Proprietary and Established Names:

Medisign MM3000 Blood Glucose Monitoring System
Medisign MM3000 Multi Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose test system
   21 CFR 862.1660, Quality Control Material (assayed and unassayed)
   21 CFR 862.2100, Calculator/data processing module for clinical use

2. Classification:
   Class II, Class I (reserved)

3. Product code:
   NBW, System, Test, Blood Glucose, Over The Counter
   CGA, Glucose Oxidase, Glucose
   JJX, Single (specified) analyte controls (assayed and unassayed)
   JQP, Calculator/data processing module for clinical use

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:

   Medisign MM3000 Blood Glucose Monitoring System:
   The Medisign® MM3000 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, forearm or palm. The Medisign® MM3000 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Medisign® MM3000 meter contains some speaking functions but is not intended for use by the visually impaired.

   The Medisign® MM3000 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 Medisign® MM3000 Blood Glucose Monitoring System 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 Medisign® MM3000Test Strips are for use with the Medisign® MM3000 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

   The Medisign® Glucose Control Solutions are intended for use with the Medisign® MM3000 meter and Medisign® MM3000 Test Strips as a quality control check to verify the meter and test strip are working together properly, and that the test is performing correctly.

   The Medisign Link Diabetes Management Software is personal computer(PC) based software intended for use in home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for effective controlling and managing blood glucose.

   Medisign MM3000 Multi Blood Glucose Monitoring System
   The Medisign® MM3000 Multi Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) fresh capillary whole blood from fingertip, palm, or forearm. The Medisign® MM3000 Multi Blood Glucose Monitoring System 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 a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices. The Medisign® MM3000 Multi meter contains some speaking functions but is not intended for use by the visually impaired.

The Medisign® MM3000 Multi Blood Glucose Monitoring System 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 Medisign® MM3000 Multi Blood Glucose Test Strips are for use with the Medisign® MM3000 Multi Blood Glucose Meter to quantitatively measure glucose (sugar) fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The Medisign® MM3000 Glucose Control Solutions are intended for use with the Medisign® MM3000 meter and Medisign® MM3000 Test Strips as a quality control check to verify the meter and test strip are working together properly, and that the test is performing correctly.

The Medisign Link Diabetes Management Software is personal computer(PC) based software intended for use in home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for effective controlling and managing blood glucose.

3. Special conditions for use statement(s):

- The Medisign MM3000 Blood Glucose Monitoring System is for single-patient use only.
- The Medisign MM3000 Multi Blood Glucose Monitoring System should only be used with single-use, auto-disabling lancing devices.
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients.
- AST measurements should never be used to calibrate continuous glucose monitors (CGMSs).
- AST measurements should never be used in insulin dosing calculations.

4. Special instrument requirements:

Medisign MM3000 Blood Glucose Meter
Medisign MM3000 Multi Glucose Meter

I. Device Description:

Medisign MM3000 Blood Glucose Monitoring System components include the Medisign MM3000 Blood Glucose Meter, the Medisign MM3000 Test Strips, a lancing device, sterile lancets, and a carrying bag including user manual, quick reference manual and log book. The Medisign MM3000 Blood Glucose Meter is provided as a meter only. Medisign MM3000 Test Strips, Medisign Glucose Control Solutions (1, 2, 3 levels), diabetes management software, and data transporting cable are sold separately.

Medisign MM3000 Multi Blood Glucose Monitoring System components include the Medisign MM3000 Multi Blood Glucose Meter, the Medisign MM3000 Multi Blood Glucose Test Strips, and a carrying bag including user manual, quick reference manual and log book. The Medisign MM3000 Multi Blood Glucose Meter is provided as a meter only. Disposable lancing device, Medisign MM3000 Multi Blood Glucose Test Strips, Medisign MM3000 Glucose Control Solutions (1, 2, 3 levels), diabetes management software, and data transporting cable are sold separately.

Medisign MM3000 Blood Glucose Test Strips and Medisign MM3000 Multi Blood Glucose Test Strips are available in vials or in aluminum foil packs.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Medisign MM1100 Blood Glucose Monitoring System;
   Medisign MM1100 Multi Blood Glucose Monitoring System

2. Predicate K number(s):

   k111456

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	Predicate Device: Medisign MM1000, 1100, 1200 (and Multi) Blood Glucose Monitoring System (k111456)	Candidate Device: Medisign MM3000 (and Multi) Blood Glucose Monitoring System
Intended Use/Indications for Use	Intended for the quantitative measurement of the concentration of glucose as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	Same

Calibration Coding	Auto code	Same
Test range	20 - 600 mg/dL	Same
Hematocrit range	30 - 55%	Same
Operating Temperature	50-104ºF	Same
Operating Humidity	10-90% RH	Same
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, forearm, palm	Same
Sample volume	0.5 µL	Same
Sample test time	5 seconds	Same
Battery	Two(2) 3.0V Lithium batteries(CR2032)	Two(2) 1.5V Alkaline batteries(LR03, AAA)
Memory	300 results with date, time, and flag with 14 day average	500 results with date, time, and flag with 7, 14, and 28 day averages
Test Strip Expiration Date	18 months (3 months after opening)	24 months (3 months after opening)
Glucose Control Solution Levels	Level A Level B	Level 1 Level 2 Level 3
Alarm Function	N/A	Three (3) different interval settings available
Hypoglycemic Indicator	N/A	Available
Averaging Results	14 days	7, 14, and 28 days
Voice Function	N/A	Available
Test Strip Packaging	Desiccant Vial	Desiccant Vial or waterproof aluminum foil pack for single test strip packing

Similarities and Differences of the control solution		
Item	Predicate Device Rightest Control Solutions GC550 (k092052)	Candidate Device Rightest Control Solutions GC700
Intended use/Indications for Use	To check that the meter and test strips are working together properly.	Same
Matrix	Viscosity-adjusted, aqueous liquid	Same
Number of levels	2 levels (Levels A and B)	3 levels (Level 1, 2, and 3)

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

- IEC 61010-1: 2010, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
- IEC 61010-2-101: 2002, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 61326-1: 2006, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
- IEC 61326-2-6: 2006, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – in vitro diagnostic (IVD) medical equipment
- ISO 10993-5: 2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISOO 10993-10: 2002, Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
- ISO 15197, 2003: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
- ISO 14971:2012, Medical devices – Application of risk management to medical devices.
- EN 13640: 2002, Stability testing of in vitro diagnostic reagents
- CLSI EP7-A2: 2005, Interference Testing in Clinical Chemistry; Approved Guideline.
- CLSI EP6-A: 2003, Evaluation of the linearity of quantitative measurement procedures: A statistical approach

L. Test Principle:

Medisign Blood Glucose Monitoring System measures the glucose in the whole blood sample by using a small electrical current produced by a chemical reaction between the glucose in the blood and glucose oxidase (GOx) on the test strip. This current is proportionally converted to the amount of glucose in the blood sample to display as the blood glucose result. Glucose measurements are reported as plasma equivalents.

M. Performance Characteristics (if/when applicable):

Medisign MM1100 Blood Glucose Monitoring System and Medisign MM1100 Multi Blood Glucose Monitoring System are the same except in name and intended use (single- vs. multiple-patient use). Therefore, only one set of performance data is needed.

1. Analytical performance:

   a. *Precision/Reproducibility:*

      The repeatability evaluation was performed by adjusting venous blood to 5 glucose levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400). All

samples were tested on 3 lots of test strips with ten Medisign MM3000 meters. All samples were also tested on the YSI 2300 analyzer to generate the expected values. Results are summarized below:

Within-run precision for glucose:

Glucose Level (mg/dL)	Lot	Number of tests	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 to 50	A	300	40.7	1.1	2.7
	B		40.5	1.5	3.8
	C		40.7	2.1	5.1
51 to 110	A	300	91.3	1.7	1.9
	B		91.8	2.4	2.7
	C		90.6	2.5	2.8
111 to 150	A	300	133.6	3.4	2.5
	B		132.1	2.9	2.2
	C		134.0	4.0	3.0
151 to 250	A	300	220.4	5.5	2.5
	B		220.4	5.5	2.5
	C		218.2	7.6	2.0
251 to 400	A	300	374.6	7.0	1.9
	B		373.0	8.1	2.2
	C		372.1	7.6	2.0

Between-day precision was evaluated using three levels of glucose control solutions(Level 1, 2, and 3). Each sample was measured in duplicate with three test strip lots and 10 Medisign MM3000 glucose meters. These tests were performed over 10 days, for a total of 300 tests per glucose level. Results are summarized below.

Between-day precision for glucose:

Glucose Level (mg/dL)	Lot	Number of tests	Mean (mg/dL)	SD (mg/dL)	% CV
40	A	300	40	1.3	3.3
	B		40	1.2	3.0
	C		38	1.0	2.7
85	A	300	77	2.0	2.6
	B		72	2.5	3.5
	C		75	2.3	3.1
260	A	300	263	7.3	2.8
	B		263	7.3	2.8
	C		260	6.9	2.7

b. Linearity/assay reportable range:

Linearity was evaluated using one test strip lot and 9 mixed pools of venous blood samples ranging in glucose concentrations (as measured by YSI) of 19, 45, 88, 168, 233, 345, 470, 535, 618 mg/dL. Each level was measured 20 times and the values from the Medisign MM3000 glucose meter were compared with those obtained from YSI 2300. Results from regression analysis:

$$y = 0.998x - 6.24;\ R^2 = 0.999$$

The results of the study support the sponsor's claimed glucose measurement range of 20-600 mg/dL.

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

Traceability:
The Medisign MM3000 and Medisign MM3000 Multi Blood Glucose Monitoring Systems are traceable to the NIST SRM #917c reference material. The method comparison study was performed using the YSI 2300 Glucose Analyzer as the reference method (see Section 2.a. below).

Test Strip Stability:
Test strip stability was assessed in real time studies. The stability testing protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims shelf life stability of 24 months and an open-vial stability of 3 months at the recommended storage temperatures of 39°F-86°F and 10-90% RH.

Control Solution Value Assignment and Stability:
Value assignment: Three levels of aqueous control solutions (levels 1 to 3) are available for use with the Medisign MM3000 Blood Glucose Monitoring System. Value assignment for use of the control solutions with the Medisign MM3000 glucose test strips is based on measurements using the YSI 2300. The values for each of the control solutions are assigned by repeat analysis using 25 Medisign test strips per lot of test strips and five Medisign MM3000 glucose meters. The mean, SD and CV are used to establish the acceptable ranges for the test strips. The range for each control solution is provided in the labels of the test strips.

Stability Testing: Stability was assessed using real-time 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 24 months and an open-vial stability claim of 3 months when stored at the recommended storage temperatures of 4°-30°C (39-86°F).

d. Detection limit:

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

e. Analytical specificity:

Interference studies were performed by spiking venous blood with three levels of glucose concentrations (70-100, 140 to 180 and 250 to 350 mg/dL). Each of these samples was divided into a test group and a control group and each of 19 potential endogenous and exogenous interfering substances was added to the test group. Each compound was tested at two concentrations, normal/therapeutic and high/toxic concentrations.

Each sample was analyzed 5 times with the Medisign MM3000 glucose meter and the % difference between the interferent containing sample and the control sample calculated. The sponsor defines no significant interference as within ±10% difference relative to the control sample. 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		Salicylic Acid	50
Ascorbic Acid	5		Tetracycline	4
Bilirubin	40		Tolbutamide	100
Cholesterol	500		Triglycerides	1500
Creatinine	30		Uric Acid	40
Dopamine	13		Maltose	450
Ibuprofen	50		Galactose	10
L-Dopa	5		Lactose	5.0
Methyldopa	2.5		Xylose	100
Hemoglobin	500		Caffeine	10
Ephedrine	10		Pyruvic Acid	10

The following limitations regarding potential interference are included in the Test Strip Insert:
Interferencecs: Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin c) and other interferent substances in blood at normal/therapeutic concentrations do not significantly affect results, however, abnormally high concentrations in blood may cause inaccurate results.

All test results using MM3000 Blood Glucose Monitoring System showed % bias within ±10% between the test and control groups for the toxic level of interference substance at two levels (140~180mg/dL, 250~350mg/dL) of

glucose concentration.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy:
To assess system accuracy, results from the Medisign MM3000 Blood Glucose Monitoring System were compared to a reference method, YSI 2300. Capillary samples from 106 participants with glucose concentrations ranging from 36 to 438 mg/dL were tested using three test strip lots. To obtain extreme blood glucose concentrations 5 samples ≤ 47 mg/dL and 5 samples ≥ 412 mg/dL were altered. For the altered samples, capillary blood samples were collected with an anticoagulant and incubated to allow glucose to hydrolyse (≤ 47 mg/dL) or the glucose was supplemented (≥ 412). The results relative to YSI are summarized in the tables below:

For glucose concentrations <75 mg/dL

Meter	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
M3A-0000034	12/18 (66.7%)	18/18 (100%)	18/18 (100%)
M3A-0000035	11/18 (61.1%)	18/18 (100%)	18/18 (100%)

For glucose concentrations ≥ 75 mg/dL

Meter	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
M3A-0000034	44/88 (50%)	78/88 (88.6%)	88/88 (100%)	88/88 (100%)
M3A-0000035	41/88 (46.6%)	77/88 (87.5%)	87/88 (98.9%)	88/88 (100%)

Linear Regression Analysis:

Comparison vs. YSI	Range of values	Slope and y-intercept	R
M3A-0000034	36-438	y=0.993x-0.437	0.988
M3A-0000035	36-438	y=0.997x-0.858	0.985

Alternative Site Testing:
Alternative Site testing was performed by healthcare professionals and the results from the Medisign MM3000 Blood Glucose Monitoring System were compared to a reference method, YSI 2300. Capillary samples from 105 participants with glucose concentrations ranging from 43 to 484 mg/dL were tested using three test strip lots. The results relative to YSI are summarized in the tables below:

For glucose concentrations <75 mg/dL

Site	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Palm vs. YSI	6/10 (60%)	9/10 (90%)	10/10 (100%)
Forearm vs. YSI	7/10 (70%)	9/10 (90%)	10/10 (100%)

For glucose concentrations ≥ 75 mg/dL

Site	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Palm vs. YSI	56/95 (58.9%)	83/95 (87.4%)	93/95 (97.9%)	95/95 (100%)
Forearm vs. YSI	54/95 (56.8%)	82/95 (86.3%)	93/95 (97.9%)	95/95 (100%)

Linear Regression Analysis:

Site	Range of values	Slope and y-intercept	R
Palm vs. YSI	68-462	y=0.958x+3.201	0.985
Forearm vs. YSI	68-462	y=0.986x-0.928	0.988

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 Medisign MM3000 Blood Glucose Monitoring System in the hands of the intended users the sponsor performed a study with 180 lay user participants, who collected samples at three study locations with three test strip lots. Study participants tested their finger, palm, and forearm. Results were analyzed by comparing blood glucose results from the Medisign MM3000 glucose meter obtained by the lay user against the YSI 2300 reference value. The unaltered capillary blood samples ranged from 54-460 mg/dL as measured by YSI. The results are summarized in the tables below:

User vs. YSI:
For glucose concentrations <75 mg/dL

	N	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	8	4/8 (50%)	7/8 (87.5%)	8/8 (100%)
Palm	12	9/12 (75.0%)	12/12 (100%)	12/12 (100%)
Forearm	12	9/12 (75.0%)	12/12 (100%)	12/12 (100%)

For glucose concentrations ≥ 75 mg/dL

	N	Within ± 5 %	within ± 10 %	within ± 15 %	Within ± 20 %
Finger	172	70/172 (40.7%)	132/172 (76.7%)	167/172 (97.1%)	172/172 (100%)
Palm	93	41/93 (44.1%)	74/93 (79.6%)	89/93 (95.7%)	92/93 (98.9%)
Forearm	93	44/93 (47.3%)	75/93 (80.6%)	87/93 (93.5%)	93/93 (100%)

Linear Regression Analysis:

Site	Sample Range	Slope and y-intercept	r
Finger	54-460	y=0.991x-0.954	0.980
Palm	43-484	y=0.982x – 4.035	0.990
Forearm	43-484	y=0.992x – 3.024	0.987

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Expected glucose values without diabetes:

Status	Range
Before eating	<100 mg/dL
Two hours after meals	<140 mg/dL

American Diabetes Association, Clinical Practice Recommendations (2013) Diabetes Care, Vol. 36, Supplement 1, p S1 - S100.

N. Instrument Name:

Medisign MM3000 Blood Glucose Monitoring System
Medisign MM3000 Multi Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and requires a minimum 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 _____ 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, palm, and forearm only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:
   The meter identifies the test strip code automatically; therefore, no coding is required by the user. The labeling includes instructions for the user to try another test strip if the code numbers don't match and to contact Customer Service if the problem persists.

6. Quality Control:
   Three levels of aqueous glucose control solutions are available with this system. The glucose control solutions are sold separately. Control solution test mode is provided to separate the control solution test results from those produced by whole blood. Control solution test results are not included the calculation for the Days Average result. Recommendations on when to test the control materials are provided in the labeling. The control solution results are not included in the averaging results. An acceptable range for each control level is printed on the test strip 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) Hematocrit Study: The effect of different hematocrit levels on the performance of the Medisign MM3000 Blood Glucose Monitoring System was evaluated using venous whole blood samples with hematocrit levels 30, 42, and 55% spiked with glucose to achieve 6 concentrations ranging from 38 to 503 mg/dL (38, 99, 190, 313, 396, and 503 mg/dL). Each sample was then tested 10 times using the Medisign MM3000 glucose meter and the values were compared with those obtained from YSI-2300 analyzer. The % biases relative to YSI were acceptable within the claimed hematocrit range of 30 to 55%.

2) Altitude study: This study was performed with 5 venous blood samples ranging from 78 to 490 mg/dL (78, 127, 240, 395, and 490 mg/dL) using YSI plasma reference method. Testing was performed at altitudes of sea level and 11,480 feet using a chamber to simulate high altitude conditions. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,000 feet (3048 meters) have no significant effect on blood glucose measurements from the Medisign MM3000 glucose meter.

3) Sample volume study: The sponsor performed a study to verify the test strip minimum sample volume requirement. Blood samples were tested at five sample volumes (0.3, 0.4, 0. 5, 0.6, and 0.7 μL) and values obtained were compared to YSI values. Results support the claimed minimum sample volume of 0.5 μL

4) Temperature and humidity studies: The sponsor performed temperature and humidity studies using venous blood samples at 3 glucose concentrations to evaluate temperatures ranging from 10^{o}C to 40^{o}C and relative humidity from 10% to 90%. Meter results were compared to YSI values. Six temperature and

humidity combinations were tested including 10°C at 10% and 90% RH, 22°C at 10% and 90% RH and40°C at 10% and 90% RH. 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 39 to 104°F (10 to 40°C) with relative humidity of 10 to 90%.

5) Infection Control Studies: The device is intended for single-patient (MM3000 Blood Glucose Monitoring System) andmultiple-patient (MM3000 Multi Blood Glucose Monitoring System) use. Disinfection efficacy testing on the surface materials of the meter by an outside commercial testing laboratory demonstrated complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes® Disinfecting Towelettes with EPA number 46781-8. Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 11,000 cleaning and disinfection cycles designed to simulate 3 years of device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6) EMC testing was evaluated and certified by ONETECH Corp. and Verification of Compliance certificates provided.

7) A readability assessment was provided to demonstrate that the User Manual, test strip package insert and control solution package insert were each written at the 8th grade level.

8) Customer service is available 24 hours a day/7 days a week/365 day a year by calling 1-888-885-6677.

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.