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

A. 510(k) Number:

k111456

B. Purpose for Submission:

New device

C. Measurand:

Glucose in capillary whole blood from the finger, palm and forearm

D. Type of Test:

Quantitative, amperometric, glucose oxidase

E. Applicant:

Tianjin Empecs Medical Device Co., Ltd.

F. Proprietary and Established Names:

Medisign MM1000 Blood Glucose Monitoring System
Medisign MM1100 Blood Glucose Monitoring System
Medisign MM1200 Blood Glucose Monitoring System

Medisign MM1000 Multi Blood Glucose Monitoring System
Medisign MM1100 Multi Blood Glucose Monitoring System
Medisign MM1200 Multi Blood Glucose Monitoring System

Medisign Glucose Control Solutions

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345 Glucose Test System

   21 CFR 862.1660 Quality Control Material

2. Classification:

   Class II

   Class I, reserved

3. Product code:

   NBW - Blood glucose test system, over the counter

   CGA - Glucose oxidase, glucose test system

   JJX - Single (Specified) Analyte Controls

4. Panel:

   Clinical Chemistry - 75

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below.

2. Indication(s) for use:

   Medisign MM1000, MM1100, and MM1200 Blood Glucose Monitoring Systems

   The systems are intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes, is intended for self-testing by persons at home, is for single-patient use only, and should not be shared. It is intended for use outside the body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates. The alternative site testing (palm and forearm) in this system can only be used during steady-state blood glucose conditions.

   The Medisign MM1000, MM1100, and MM1200 test strips are to be used with the Medisign MM1000, MM1100, and MM1200 Blood Glucose Meters, respectively, to monitor glucose concentration of capillary whole blood. Medisign MM1000, MM1100, and MM1200 test strips and associated meters are for use in fingertip, forearm, and palm testing. The strips are intended for self-testing by persons at home, are for single-patient

use only, and should not be shared. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

For over the counter use only.

Medisign MM1000 Multi, MM1100 Multi, and MM1200 Multi Blood Glucose Monitoring Systems

The systems are intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes and may be used for testing multiple patients in professional healthcare settings. It is intended for use outside of the body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates. The alternative site testing (palm and forearm) in this system can only be used during steady-state blood glucose conditions. Only auto-disabling, single use lancing device should be used with this system.

The Medisign MM1000 Multi, MM1100 Multi, and MM1200 Multi Blood Glucose Test strips are to be used with Medisign MM1000 Multi, MM1100 Multi, and MM1200 Multi Blood Glucose Meters, to monitor glucose concentration of capillary whole blood. Medisign MM1000 Multi, MM1100 Multi, and MM1200 Multi Blood Glucose Test strips and associated meters are for use in fingertip, forearm, and palm testing. The systems are intended for use for multiple-patient use by health care professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system to prevent transferring disease by blood. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

For prescription use only.

Medisign Glucose Control Solutions

Medisign Glucose Control Solutions are for use with Medisign Brand Blood Glucose Meters and Medisign Test Strips to check that the meter and test strips are working together properly. Medisign Glucose Control Solutions are intended for use by healthcare professionals and people with diabetes mellitus at home. Medisign Glucose Control Solutions are for in vitro diagnostic use.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only.
Not for neonatal use
Not for screening or diagnosis of diabetes mellitus
Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients

Alternative site testing (AST) should only be performed during periods of steady-state

blood glucose conditions (when glucose is not changing rapidly). Results from AST should not be used to calibrate continuous glucose monitors (CGMs). Results from AST should not be used in insulin dose calculations.

Single-patient use systems are for use on single patients only and should not be shared Multiple-patient use systems should only use single use, auto disabling lancing devices.

4. Special instrument requirements:

Medisign MM1000 Glucose Meter
Medisign MM1100 Glucose Meter
Medisign MM1200 Glucose Meter

Medisign MM1000 Multi Glucose Meter
Medisign MM1100 Multi Glucose Meter
Medisign MM1200 Multi Glucose Meter

I. Device Description:

Medisign MM1000, MM1100, and MM1200 blood glucose monitoring systems are for single-patient use for the measurement of glucose in whole blood. The systems consist of a blood glucose meter, blood glucose test strips, and a carrying bag including user manual, quick reference manual, and log book. Some kits do not include blood glucose test strips. Blood glucose test strips, blood glucose control solutions (levels A and B), check strip, diabetes management software, and data transporting cable are sold separately.

Medisign MM1000 Multi, MM1100 Multi, and MM1200 Multi blood glucose monitoring systems are for multiple-patient use for the measurement of glucose in whole blood. The systems consist of a blood glucose meter, blood glucose test strips, and a carrying bag including user manual, quick reference manual, and log book. Some kits do not include blood glucose test strips. Disposable lancing device, blood glucose test strips, blood glucose control solutions (levels A and B), check strip, diabetes management software, and data transporting cable are sold separately.

Each box of test strips contains one vial of 10 test strips, one vial of 25 test strips, one vial of 50 test strips, or two vials of 25 test strips. Each test strip contains glucose oxidase (A. Niger). Each box of control solutions (levels A and B) contains one vial of aqueous control solution with approximately 120 mg/dL glucose for level A and 320 mg/dL glucose for level B.

J. Substantial Equivalence Information:

1. Predicate device name:

OneTouch Ultra 2 Blood Glucose Monitoring System (k053529)
OneTouch Ultra Control Solution (k022769)

2. Predicate 510(k) number:

   See predicate device name above.

3. Comparison with predicate:

Comparison Table: Meter and Test Strips		
Item	New Device (k111456)	Predicate (k053529)
Intended Use	Intended for quantitative measurement of glucose.	Same
Detection method	Amperometry	Same
Enzyme	Glucose oxidase (Aspergillus niger)	Same
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, palm, forearm	Same
Calibration	Autocoding	Manual coding by user
Measurement Range	20-600 mg/dL	Same
Blood Sample Volume	0.5 uL	1 uL
Reaction Time	5 seconds	Same
Memory Capability	300 test results	500 test results
Operating Conditions	10-40°C	6-44°C
Battery Type	DC 3V CR2032 Lithium battery	Same
Connectivity	USB cable	Same
Software	Medisign Link-Diabetes Management Software	OneTouch Diabetes Management Software

Comparison Table: Medisign Glucose Control Solution		
Item	New Device (k111456)	Predicate (k022769)
Intended Use	Check performance of test system	Same
Levels	2 (levels A and B)	1 level
Color Indicator	Red	Same
Matrix	Buffered aqueous solution of D-glucose	Same
Operating Conditions	20-25°C	Same
Storage Conditions	4-30°C	Below 30°C

K. Standard/Guidance Document Referenced:

1. CLSI EP6-A: 2003. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.
2. CLSI EP7-A2: 2005. Interference Testing in Clinical Chemistry.
3. EN 61010-1:2001. Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 1. General requirements.
4. IEC/EN 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.
5. EN 61326-1:2006. Electrical equipment for measurement, control, and laboratory use. EMC Requirements. General requirements.
6. EN 61326-2-6:2006. Electrical equipment for measurement, control, and laboratory use. EMC Requirements. Particular requirements-*in vitro* diagnostic medical equipment.
7. ISO 10993-5:2009. Biological evaluation of medical devices, Part 5: Tests for *in vitro* cytotoxicity.
8. ISO 10993-10:2002. Biological evaluation of medical devices, Part 10: Tests for irritation and delayed-type hypersensitivity.
9. ISO 11137-1:1995. Sterilization of health care products. Requirements for validation and routine control of a sterilization process for medical devices.
10. ISO 13640:2002. Stability Testing of *In Vitro* Diagnostic Reagents. (*In Vitro* Diagnostics).
11. ISO 14971:2007. Medical devices-Application of risk management to medical devices.
12. ISO 15197: 2003. *In vitro* diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

L. Test Principle:

Glucose in the blood sample reacts with glucose oxidase on the test strip and an electrical current is produced. This current is measured by the meter and displayed as the blood glucose result. The strength of these currents changes with the amount of glucose in the blood sample. The meter automatically interprets this reaction. Glucose measurements are reported as plasma equivalents.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The Medisign MM1000, MM1100, MM1200, MM1000 Multi, MM1100 Multi, and MM1200 Multi blood glucose monitoring systems are identical in technological characteristics. All six test systems use the same test strips and are identical with the exception of their names, meter cover appearance, and indications for use (single- vs. multiple-patient use); therefore, one set of performance data was provided.

a. Precision/Reproducibility:

Repeatability studies were carried out by testing venous blood at five venous blood glucose concentrations (HCT 42%) ranging from 42-332 mg/dL. Three lots of MM1000 glucose test strips were tested on ten MM1000 glucose meters with ten replicates per meter. To evaluate intermediate precision, the sponsor tested three levels of control solutions on ten MM1000 glucose meters and three lots of MM1000 glucose test strips over the course of 10 days. The mean, standard deviation (SD), and coefficients of variation (CV) were determined for each level as summarized below:

Repeatability Data Summary			
Venous Blood Samples			
Lot 1			
Blood Glucose Level	**Grand Mean (mg/dL)**	**Pooled SD (mg/dL)**	**Pooled CV (%)**
1	42	1.6	3.8
2	85	2.0	2.3
3	135	2.9	2.1
4	205	3.9	1.9
5	337	8.5	2.5
Lot 2			
Blood Glucose Level	**Grand Mean (mg/dL)**	**Pooled SD (mg/dL)**	**Pooled CV (%)**
1	43	1.9	4.4
2	86	2.3	2.7
3	132	3.2	2.4
4	201	4.5	2.2
5	334	6.8	2.0
Lot 3			
Blood Glucose Level	**Grand Mean (mg/dL)**	**Pooled SD (mg/dL)**	**Pooled CV (%)**
1	44	1.9	4.2
2	85	2.1	2.5
3	136	2.6	1.9
4	202	3.6	1.8
5	334	8.4	2.5
Intermediate Precision Data Summary			
Control Samples			
Lot 1			
Blood Glucose Level	**Grand Mean (mg/dL)**	**Pooled SD (mg/dL)**	**Pooled CV (%)**
A	74	1.6	2.2
B	256	5.8	2.3
Lot 2			
Blood Glucose Level	**Grand Mean (mg/dL)**	**Pooled SD (mg/dL)**	**Pooled CV (%)**
A	73	1.7	2.3
B	262	5.9	2.2
Lot 3			
Blood Glucose Level	**Grand Mean (mg/dL)**	**Pooled SD (mg/dL)**	**Pooled CV (%)**
A	74	1.9	2.5

B	262	6.3	2.4

b. Linearity/assay reportable range:

A linearity study was carried out using nine different levels of venous whole blood sample ranging from 18, 48, 65, 147, 272, 374, 452, 561, and 610 mg/dL (42% HCT) as determined by the YSI reference method. Samples were altered to reach the low and high end of the glucose concentration range. Each glucose level was measured with one lot of glucose test strips on two MM1100 glucose meters. Least-square regression analysis is summarized below.

Linearity Data Summary	
Regression Data	
Equation	y=1.026x-3.57
Slope - 95% CI	1.001 to 1.014
Intercept - 95% CI	-8.428 to -3.545
r^2	0.998

The claimed reportable range of the MM1000, MM1100, MM1200, MM1000multi, MM1100multi, and MM1200 multi blood glucose monitoring systems is 20 to 600 mg/dL. Samples below or above the claimed measuring range are flagged by the meter as "LO" or "HI", respectively.

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

Traceability

The Medisign blood glucose monitoring systems are factory calibrated and further calibration by the user is not necessary for operation. The calibration is traceable to NIST SRM #917c.

Test Strip Stability

Stability testing protocols and acceptance criteria for the Medisign test strips were reviewed and found to be acceptable. The manufacturer claims a shelf life stability of 18 months and an open-vial stability of 3 months at the recommended storage temperatures of 4-30°C.

Controls Value Assignment and Stability

Value assignment for the control solutions is based on repeat testing using twenty-five Medisign test strips for every lot of test strips and five Medisign glucose meters. Value ranges are as follows:

Control Solution Level A: Target value is 120 mg/dL.

Control Solution Level B: Target value is 320 mg/dL.

Stability testing protocols and acceptance criteria for the glucose control solutions were reviewed and found to be acceptable. The manufacturer claims a shelf life stability of 18 months and an open-vial stability of 3 months at the recommended storage temperatures of 4-30°C.

d. Detection limit:

The measuring range of the Medisign blood glucose monitoring systems is 20 to 600 mg/dL. This range was verified by the linearity study (see section M.1.b of this decision summary).

e. Analytical specificity:

Interferences studies were performed by adding common endogenous and exogenous substances to two sets of venous blood samples at 140-180 mg/dL and 250-350 mg/dL plasma glucose and calculating bias relative to a control of the same samples. Studies done by collecting five replicates using one test strip lot at a therapeutic and a toxic level of each common endogenous and exogenous compound. Significant interference was defined by the sponsor as >10% bias. No significant interference was observed up to the levels shown in the table below for the following interfering substances:

Table pending

Substance	**No Interference at Listed Level (ug/mL)**
Endogenous Substance	
Bilirubin	400
Cholesterol	5000
Creatinine	300
Hemoglobin	5000
Triglycerides	5000
Uric Acid	400
Exogenous Substance	
Acetaminophen	200
Ascorbic Acid	50
Caffeine	100
Dopamine	130
Ephedrine	100
Galactose	100
Ibuprofen	500
L-Dopa	50
Maltose	4500
Methyl-Dopa	25

Pyruvic Acid	100
Salicylic Acid	500
Tetracycline	40
Tolbutamide	1000
Xylose	1000

The sponsor has added the following limitation on the product labeling: "Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C) and other interferent substances in normal blood or normal therapeutic concentrations, do not significantly affect results however, abnormally high concentrations in blood may cause inaccurate results."

"Grossly lipemic patient samples have not been tested and are not recommended for testing with the Medisign System."

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy

The accuracy of the Medisign MM1000 blood glucose monitoring system was evaluated by testing 108 capillary samples on three test strip lots in duplicate for each sample and two meters. From these, 22 samples were altered to achieve the low and high end of the claimed assay range. Measurements obtained with the Medisign MM1000 test system were compared to those obtained with the YSI-2300 reference method. Samples covered a plasma glucose range of 30-534 mg/dL. Results were subjected to acceptance criteria described in the ISO 15197 standard. The accuracy data are summarized below.

Accuracy Study Regression Statistics		
	Meter 1	Meter 2
Number of samples (n)	108	108
Range of YSI Glucose Values (mg/dL)	30 - 534	30 - 534
Slope	1.005	1.002
95% CI	0.971 to 1.030	0.971 to 1.033
Intercept	0.6506	0.815
95% CI	-5.542 to 6.843	-5.858 to 7.487
R square	0.977	0.974

Accuracy Study Results

Glucose < 75 mg/dL				
	Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL	
Meter 1	9/20 (45%)	17/20 (85%)	20/20 (100%)	
Meter 2	8/20 (40%)	15/20 (75%)	20/20 (100%)	
Glucose ≥ 75 mg/dL				
	Within ± 5 %	Within ±10 %	Within ± 15 %	Within ± 20%
Meter 1	44/88 (50%)	68/88 (77.3%)	83/88 (94.3%)	87/88 (98.9%)
Meter 2	37/88 (42%)	69/88 (78.4%)	81/88 (92%)	86/88 (97.7%)

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 Evaluation:

In the user performance evaluation, capillary fingerstick data from 156 lay users on three test strip lots on the Medisign MM1000 system were compared to glucose values obtained with the YSI reference method covering the glucose range of 40-376 mg/dL. In addition, an AST study was provided in which 104 subjects measured their blood glucose from the palm and forearm using three test strip lots and three Medisign MM1000 meters. Results were compared to the YSI reference method. The glucose range covered in this study was 40-376 mg/dL. Study results are summarized below:

User Performance Study Regression Statistics				
	Lay-users vs. YSI			Professionals vs. YSI
Site	Fingertip	Palm	Forearm	Fingertip
Number of samples (n)	156	104	104	156
Range of YSI Glucose Values (mg/dL)	40-376	40-376	40-376	40-376
Slope	0.966	0.973	0.974	0.969
95% CI	0.941 to 0.991	0.946 to 1.000	0.948 to 1.001	0.945 to 0.993

Intercept	4.847	1.817	1.442	5.182
95% CI	0.630 to 9.065	-2.989 to 6.622	-3.333 to 6.222	1.064 to 9.301
R square	0.975	0.981	0.981	0.976

User Performance Study Results				
Glucose < 75 mg/dL				
Fingertip	Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL	
Lay-User vs. YSI	3/16 (18.8%)	9/16 (56.3%)	16/16 (100%)	
Professional vs. YSI	5/16 (31.3%)	12/16 (75%)	16/16 (100%)	
Palm	Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL	
Lay-User vs. YSI	7/12 (58.3%)	12/12 (100%)	12/12 (100%)	
Forearm	Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL	
Lay-User vs. YSI	8/12 (66.7%)	12/12 (100%)	12/12 (100%)	
Glucose ≥ 75 mg/dL				
Fingertip	Within ± 5 %	Within ±10 %	Within ± 15 %	Within ± 20%
Lay-User vs. YSI	63/140 (45%)	118/140 (84.3%)	136/140 (97.1%)	137/140 (97.9%)
Professional vs. YSI	63/140 (45%)	109/140 (77.9%)	134/140 (95.7%)	140/140 (100%)
Palm	Within ± 5 %	Within ±10 %	Within ± 15 %	Within ± 20%
Lay-User vs. YSI	48/92 (52.2%)	81/92 (88%)	91/92 (98.9%)	92/92 (100%)
Forearm	Within ± 5 %	Within ±10 %	Within ± 15 %	Within ± 20%
Lay-User vs. YSI	51/92 (55.4%)	83/92 (90.2%)	92/92 (100%)	92/92 (100%)

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:
   The product labeling contains the following statement for non-diabetics reference values:
   "Normal blood glucose reference value for non-diabetics is as follows:
   -Before eating: < 100 mg/dL
   -2 hours after meal: <140 mg/dL
   In case results are out of reference range, please contact your healthcare professional and follow their advice."

   Reference: Diabetes Care, October 2010, vol. 33 no. 10 2184-2189.

N. Instrument Name:

Medisign MM1000 Glucose Meter
Medisign MM1100 Glucose Meter
Medisign MM1200 Glucose Meter

Medisign MM1000 Multi Glucose Meter
Medisign MM1100 Multi Glucose Meter
Medisign MM1200 Multi Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Amperometric.

   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:

   This device is intended for use with capillary whole blood from the fingertip, palm, and forearm which can be applied directly to the test strip.

5. Calibration:

   The device is factory calibrated and requires no additional calibration by the user. A check strip is provided to check the meter function.

6. Quality Control:

The sponsor recommends the use of at least one of two available Medisign control levels (levels A and B) with this system. These controls are available when requested by the customer using the contact information provided in the user manual. When the test strip is inserted into the glucose meter, control material can be measured by following the instructions for "Control Test" provided in the user manual for the meter.

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

1. Hematocrit Study - A study was performed to evaluate the blood hematocrit (HCT) effect on the performance of the Medisign MM1000 Blood Glucose Monitoring System across the measuring range of the assay. Whole blood samples were tested in replicates of 12 with the Medisign system using one lot of strips and six meters. Glucose concentrations at each HCT level (30%, 42%, and 55%) were compared to results obtained with the YSI-2300 reference method. Data from samples at 30% and 55% were also compared to results from samples at 42%. The data met acceptance criteria for the claimed HCT range. The sponsor included the following limitation in the labeling: "Hematocrit is the percentage of red blood cells in the blood. HCT levels of 30-55% were shown not to affect glucose measurements with this device. If you do not know your hematocrit level, consult with your health care professional."

2. Altitude Study - The effect of altitude was evaluated inside a chamber to simulate sea level and a high altitude condition of 11,480 feet. Three lots of the Medisign test strips were tested on three meters, ten strips per meter, with 42% HCT whole blood at five different glucose concentrations ranging from 126 to 511 mg/dL. Simulation chamber test results were compared to the YSI reference values. Average assay bias was less than ± 5%. The sponsor included a limitation in the labeling indicating that the test strip may be used at altitudes up to 10,000 feet.

3. Temperature and Humidity Studies - A study was performed to evaluate the effect of temperature and humidity on the performance of the Medisign (MM1000) Blood Glucose Monitoring System at three glucose levels (74, 120, and 302 mg/dL) using whole blood samples. Samples were tested at each glucose level with the Medisign system using one lot of strips and three meters. Glucose concentrations at each humidity level (10%, 40%, and 90% RH) and temperature combination (10°C, 23°C, and 40°C) were compared with results obtained with the YSI-2300 reference method. The study results support the manufacturer's claims of operating conditions within 10-90% RH and 10-40°C.

4. Sample Volume Study - A sample volume study using fresh whole blood samples at 61, 122, 257, 409, and 518 mg/dL glucose was performed by testing one lot of Medisign glucose test strips in replicates of 5 on one Medisign glucose meter at different sample volumes (0.3, 0.4, 0.5, 0.6, and 0.7 uL). Protocols and acceptance criteria were provided and found to be acceptable. The sponsor concluded that sample volume of ≥0.5 uL produced accurate results and samples <0.4 uL give an error code.

5. Readability Study - Flesch-Kincaid readability assessment was conducted and the results

showed that the labeling (user manual for single-patient use, test strip package inserts, and control solution package insert) were written at the 8th grade level.

6. Usability Study - A usability study was performed to assess the ease of use of the labeling by recruiting 156 lay users (ages18 to >51) who were provided with the test kit containing labeling for the US market. Participants varied in age and education, and were about evenly divided between men and women. These lay users also completed a questionnaire to respond whether the device is easy to use and the instructions for use were written in a way that makes it easy to use. The majority of the users responded the device was easy to use and the instructions were easy to understand.

7. Customer service is available 24 hours a day, 7 days a week. Toll free phone number is 1-888-885-6677 for customer support.

8. EMC Testing - EMC testing was evaluated and certified by One Tech Corp and a certificate test was issued to Tianjin Empecs on December 28, 2010.

9. Cleaning and Disinfection Studies - The device is intended for single- (Medisign MM1000, MM1100, and MM1200) and multiple- (Medisign MM1000 Multi, MM1100 Multi, and MM1200) patient use. Caviwipes disinfecting Towelettes with EPA registration #46781-8 were validated by an outside commercial testing laboratory demonstrating complete inactivation of live virus using materials from the meter. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 11,000 cleaning and disinfection cycles designed to simulate 3 years of device use. Each robustness cycle tested consisted of one pre-clean wipe and one disinfecting wipe. 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.