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

A. 510(k) Number:

k140325

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from the fingertip

D. Type of Test:

Quantitative Amperometric assay (Glucose Oxidase)

E. Applicant:

Joinsoon Medical Technology Co. Ltd.

F. Proprietary and Established Names:

Joinsoon EON L Glucose Monitoring System
Joinsoon EON LS 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)

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

3. Product code:
   NBW, System, Test, Blood Glucose, Over The Counter
   CGA, Glucose Oxidase, Glucose
   JJX, Quality Control Material (Assayed and Unassayed), if applicable

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below

2. Indication(s) for use:

   The **Joinsoon EON L Glucose Monitoring System** is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.

   The Joinsoon EON L Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes in a home setting as an aid to monitor the effectiveness of diabetes control. The Joinsoon EON L Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

   The Joinsoon EON L Glucose Monitoring System is intended to be used by a single person and should not be shared.

   The Joinsoon Single Strips are for use with the Joinsoon EON L Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips.

   The Joinsoon Control Solution is for use with the Joinsoon EON L Blood Glucose Meter and Joinsoon Single Strips as a quality control check to verify that the meter and test strips are working together properly, and that the test is performing correctly.

   The **Joinsoon EON LS Glucose Monitoring System** is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.

   The Joinsoon EON LS Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes in a home setting as an aid to monitor the effectiveness of diabetes control. The Joinsoon EON L Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The Joinsoon EON LS Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Joinsoon Snap Strips are for use with the Joinsoon EON LS Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips.

The Joinsoon Control Solution is for use with the Joinsoon EON LS Blood Glucose Meter and Joinsoon Snap Strips as a quality control check to verify that the meter and test strips are working together properly, and that the test is performing correctly.

3. Special conditions for use statement(s):
   - For In-Vitro Diagnostic Use Only
   - For over-the-counter use
   - For Self-Testing Only
   - For Single Patient Use Only
   - For over-the-counter use
   - Not for screening or diagnosis of diabetes mellitus
   - Not for use on critically ill patients, patients in shock, dehydrated patients, hypotensive, or hyper-osmolar patients
   - Do not test on neonates
   - Do not use at altitudes above 10,745 feet (3,275 m)
   - Do not perform any tests when humidity is below 10% or above 90%.

4. Special instrument requirements:

   Joinsoon EON L Blood Glucose Meter
   Joinsoon EON LS Blood Glucose Meter

I. Device Description:

The Joinsoon EON L Glucose Monitoring System contains the Joinsoon EON L Blood Glucose Meter and Joinsoon Single Strip test strips. The Joinsoon EON LS Glucose Monitoring System contains the Joinsoon EON LS Blood Glucose Meter and Joinsoon Snap Strip test strips. Both meters are no-code meters. Components of both systems include Joinsoon Control Solutions, lancet, lancing device, quick start guide, user manual, warranty card and a carrying case.

The Joinsoon Single Strip test strips have one single test pad to be used with the Joinsoon EON L glucose meter, while the Joinsoon Snap Strip test strips have 10 individual test sections which can be broken off by the user and used one at a time with the Joinsoon EON LS glucose meter.

There are 3 levels of Joinsoon Control Solution available for use with both systems; Level 1, Level 2, and Level 3. Level 2 is included in the test kit. Levels 1 and 3 can be purchased separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Lifescan OneTouch Select Glucose Monitoring System

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

   k072543

3. Comparison with predicate:

Similarities of the Blood Glucose Systems			
Item	Predicate Device Lifescan OneTouch Select Glucose Monitoring System (k072543)	Candidate Device Joinsoon EON L Glucose Monitoring System	Candidate Device Joinsoon EON LS Glucose Monitoring System
Intended Use/Indications for Use	For quantitative measurement of glucose in capillary whole blood as an aid to monitor the effectiveness of diabetes control	Same	Same
Detection method	Amperometric biosensor	Same	Same
Enzyme	Glucose Oxidase	Same	Same
Test range	20 - 600 mg/dL	Same	Same
Sample type	Capillary whole blood	Same	Same
Sample volume	0.8 µL	Same	Same

Differences of the Blood Glucose Systems			
Item	Predicate Device Lifescan OneTouch Select Glucose Monitoring System (k072543)	Candidate Device Joinsoon EON L Glucose Monitoring System	Candidate Device Joinsoon EON LS Glucose Monitoring System
Calibration Coding	Coding	Non-coding	Non-coding
Memory	350 blood or control solution test results	1000 blood and 250 control solution test results	1000 blood and 250 control solution test results
Sample sites	Fingertip, forearm, palm	fingertip	fingertip
Sample test time	5 seconds	4 seconds	4 seconds

Similarities and differences of the control solution		
Item	Predicate Device One Touch Select Control Solutions (k072543)	Candidate Device Joinsoon Control Solution
Indications for Use	To check that the glucose meter and test strips are working together properly and that the test is performing correctly.	Same
Matrix	Viscosity-adjusted, aqueous liquid.	Same
Levels	2 levels	3 levels

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

- IEC 60601-1-2, Medical electrical equipment Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility- Requirements and tests.
- IEC 61000-4-2, 2008 EMC – Part 4-2: Testing and measurement technique-Electrotstatic discharge immunity test
- IEC 61000-4-3, 2010 EMC – Part 4-3: Testing and measurement technique-Radiated, radio-frequency EMC field immunity test.
- IEC 61000-4-6, 2008 EMC – Part 4-6: Immunity to conducted disturbances, induced by RF fields.
- IEC 61000-4-8, 2009 EMC – Part 4-8: Test and Measure. Techniques Power frequency magnetic field immunity test.
- IEC 61326-1-2005 electrical equipment for measurement control and laboratory use

EMC requirements Part 1-General requirements.

- IEC 61326-1-6:2005 EMC Requirements –Part 2-6: Particular requirements-In vitro diagnostic (IVD) medical equipment.
- ISO 17544:2003 Measure of quantity in bio. Samples: Metrological traceability of values assigned to calibrators and control materials.
- CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition
- CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline.
- CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach
- CLSI EP25-A: Evaluation of stability of in vitro diagnostic reagents

L. Test Principle:

The Joinsoon EON L and EON LS Glucose Monitoring Systems use an electrochemical method based meter and dry reagent biosensor (test strip) for blood glucose testing. Both test strips, the Joinsoon Single Strips and Joinsoon Snap Strips utilize the enzyme glucose oxidase. Each non-coding test strip has a Reaction Zone with the Enzyme at one end, and contact pads at the other end. The electron accumulates on the electrode when glucose reacts with the reagent on the electrode. A current can be detected by the meter when a constant voltage is applied across the electrodes. The current is converted to a glucose concentration by an embedded transfer function in the meter. The size of the current is proportional to the amount of glucose present in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance

a. Precision/Reproducibility

Within-run (Repeatability)

Venous blood from 3 donors was adjusted with glucose to five glucose levels (30-50, 51-110, 111-150, 151-250, 251-400) and tested on 3 lots of single test strips. Venous blood from 3 other donors was adjusted with glucose to the same five glucose levels and tested on 3 lots of multiple use test strips. Ten runs were performed on each sample with 5 replicates per run/strip lot resulting in 100 replicates for each lot and glucose level tested. Results are summarized below:

Joinsoon Single Strips

Glucose Level (mg/dL)	n	Lot	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	100	1	39.3	3.01	7.66
		2	40.6	3.06	7.54
		3	42.5	2.96	6.96
51-110	100	1	98.6	3.08	3.12
		2	97.2	3.38	3.48
		3	95.8	3.53	3.68
111-150	100	1	139.9	5.23	3.74
		2	143.5	4.91	3.42
		3	144.9	4.9	3.38
151-250	100	1	234.8	8.75	3.73
		2	235.4	7.77	3.30
		3	241.2	6.86	2.84
251-400	100	1	375.0	12.27	3.27
		2	371.2	11.94	3.22
		3	368.8	10.72	2.91

Joinsoon Snap Strips

Glucose Level (mg/dL)	n	Lot	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	100	1	40.5	3.16	7.80
		2	42.2	3.14	7.44
		3	41.5	3.10	7.47
51-110	100	1	95.0	3.25	3.42
		2	91.6	3.07	3.35
		3	92.4	3.07	3.32
111-150	100	1	145.3	5.62	3.87
		2	141.1	5.31	3.76
		3	145.9	4.77	3.27
151-250	100	1	231.3	7.72	3.34
		2	236.1	7.34	3.11
		3	235.4	7.65	3.25
251-400	100	1	378.5	12.19	3.22
		2	367.6	11.19	3.04
		3	369.6	12.31	3.33

Intermediate Precision

Intermediate precision testing was evaluated using three glucose control solutions on 3 test strip lots each of the Single and Snap Strip test strips, using 10 meters. Each concentration was measured once a day for 10 days, for a total of 100 measurements Results are summarized below:

Joinsoon Single Strips:

Control Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
Level 1 40	100	1	40.3	3.0	7.47
		2	40.5	2.8	6.84
		3	40.7	3.1	7.52
Level 2 120	100	1	121.9	3.9	3.20
		2	124.2	4.1	3.30
		3	121.2	4.0	3.30
Level 3 360	100	1	360.4	7.8	2.16
		2	359.3	8.5	2.37
		3	359.4	9.5	2.64

Joinsoon Snap Strip:

Control Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
Level 1 40	100	1	40.4	2.0	4.40
		2	40.9	3.0	7.36
		3	40.9	2.8	6.82
Level 2 120	100	1	123.3	3.7	3.00
		2	121.9	4.3	3.50
		3	123.5	4.2	3.40
Level 3 360	100	1	358.9	8.5	2.37
		2	358.7	8.4	2.34
		3	360.2	9.2	2.55

b. *Linearity/assay reportable range:*

Linearity was evaluated using 3 lots of Single Strips and 3 lots of Snap Strips, with 8 meters and 20 venous whole blood samples with glucose levels ranging from 20-600 mg/dL (24, 64, 89, 120, 150, 191, 216, 250, 265, 317, 343, 395, 405, 428, 465, 496, 505, 521, 576, and 610), obtained by spiking pooled venous blood with a glucose solution. Each glucose level was analyzed 8 times over 3 test strip lots. Linear regression analysis for each test strip lot compared to the YSI resulted in:

Single Strips:

$y = 0.9969x + 0.9751$; $R^2 = 0.9995$ for Test Strip Lot 1
$y = 0.9967x – 0.0931$; $R^2 = 0.9991$ for Test Strip Lot 2
$y = 0.9986x + 0.7973$; $R^2 = 0.9995$ for Test Strip Lot 3

Snap Strips:

$y = 1.0067x + 0.6969$; $R^2 = 0.9994$ for Test Strip Lot 1
$y = 1.012x – 2.3156$; $R^2 = 0.9991$ for Test Strip Lot 2
$y = 0.9901x + 1.8869$; $R^2 = 0.9992$ for Test Strip Lot 3

The results of the study support the claimed glucose measurement range of 20 to 600 mg/dL for both test strip configurations.

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

Traceability
The system is traceable to the NIST SRM 917c reference material.

Test Strip Stability
Test strip stability was assessed in accelerated and real time studies. Testing protocols and acceptance criteria for the Single Strip and Snap Strip test strips were reviewed and found to be acceptable. The sponsor claims shelf life stability of 20 months and open vial stability of 3 months at 35.6°F-89.6°F (2°C-32°C) and 10-90% relative humidity.

Control Solution Value assignment and stability:
Value assignment of the 3 levels of Joinsoon Control Solutions was determined in an in-house procedure. The control solutions were prepared by gravimetric addition of glucose to achieve the target values of 40, 120 and 360 mg/dL for Level 1, Level2, and Level 3 respectively, and confirmed by YSI. The values for each level were assigned by repeat analysis using 100 test strips and 10 meters. The mean, SD and CV are used to establish the range for each solution, which is provided on the test strip vial labels.

Control stability was assessed using accelerated and real time testing. Protocols and acceptance criteria were reviewed and found to be acceptable to support the sponsor's shelf life claim of 30 months and open vial claim of 3 months at 2°C-32°C.

d. Detection limit:

Reference the device reportable range and the linearity studies (section M.1.b.).

e. Analytical specificity:

To assess potential interference the sponsor used venous whole blood samples adjusted to three glucose concentration intervals of 76, 166, and 285 mg/dL. Each of these samples was tested with the Joinsoon EON L Blood Glucose Meter with Single Strip test strips and the Joinsoon EON LS Blood Glucose Meter with Snap Strips and against YSI for a reference method. Each potential interfering substance was tested at a minimum of two concentrations, normal/therapeutic and high/toxic concentrations. Each sample was tested 10 times using 3 strip lots and the % difference between the

system sample and the YSI sample was calculated. Results are presented in the table below:

Potential Interfering Substance	Concentration at which no significant interference is observed (mg/dL)
Acetaminophen	10
Ascorbic acid	5
Bilirubin	40
Cholesterol	600
Creatinine	30
Dopamine	8
Galactose	60
Gentisic acid	2
Glutathione	50
Ibuprofen	40
L-ascorbic acid	3
L-Dopa	7
Maltose	200
Methyldopa	2.5
Salicylate	60
Tetracycline	10
Tolbutamide	80
Tolazamide	4
Triglycerides	3000
Urea	120
Uric acid	8
Xylose	800

The sponsor has included the following statement in the labeling for both the Joinsoon EON L and Joinsoon EON LS Glucose Monitoring Systems:

> If you are taking acetaminophen containing drugs (Tylenol etc.) or vitamin C at amounts higher than the recommended doses you may get inaccurate results with this system (Acetaminophen >10 mg/dL; Ascorbic acid (Vitamin C) >5 mg/dL).

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device

EON L Glucose Monitoring System with Single Strips:

To assess system accuracy, results from the Joinsoon EON L system were compared to the YSI reference method. Capillary fingerstick samples from 100 participants were obtained and tested using 3 lots of Joinsoon Single Strips. The range of samples tested was 30-557 mg/dL as measured on the reference (YSI). To obtain glucose concentrations < 50 mg/dL, samples were allowed to glycolize and to obtain glucose concentrations > 400 mg/dL, samples were spiked. The results relative to reference are summarized below:

for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/8 (75%)	8/8 (100%)	8/8 (100%)

for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
81/92 (88%)	90/92 (98%)	92/92 (100%)	92/92 (100%)

Results from regression analysis: $Y=1.0117x - 1.89$, $R^2 = 0.9964$

EON LS Glucose Monitoring System with Snap Strips:

To assess system accuracy, results from the Joinsoon EON L system were compared to the YSI reference method. Capillary fingerstick samples from 100 participants were obtained and tested using 3 lots of Joinsoon Single Test Strips. The range of samples tested was 25-590 mg/dL as measured on the reference (YSI). To obtain glucose concentrations < 50 mg/dL, samples were allowed to glycolize and to obtain glucose concentrations > 400 mg/dL, samples were spiked. The results relative to reference are summarized below:

for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
5/8 (62.5%)	8/8 (100%)	8/8 (100%)

for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
72/92 (78.3%)	91/92 (98.9%)	92/92 (100%)	92/92 (100%)

Results from regression analysis: $Y=0.986 + 0.836$, $R^2 = 0.9957$

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 studies:

Joinsoon EON L Glucose Monitoring System with Single Strips:
To assess the performance of the EON L System with Single Strips in the hands of intended users, the sponsor performed a study with 150 lay users. The study participants obtained their own fingerstick samples and tested them on the EON L meter and 3 lots of Single Strips using only the product labeling written in English. Within 5 minutes, a technician collected a second capillary finger sample for comparison on the YSI analyzer. The glucose concentrations of the samples tested ranged from 57to 366 mg/dL as measured on the reference. The lay user results with the EON L system compared to YSI are summarized below:

for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
12/14 (86%)	14/14 (100%)	14/14 (100%)

for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
96/136 (71%)	134/136 (98%)	136/136 (100%)	136/136 (100%)

Regression analysis results for lay user EON L vs YSI:
$Y = 1.004x – 0.46$, $R^2 = 0.996$

Joinsoon EON LS Glucose Monitoring System with Snap Strips:
To assess the performance of the EON LS System with Snap Strips in the hands of intended users, the sponsor performed a study with 150 lay users. The study participants obtained their own fingerstick samples and tested them on the EON LS meter and 3 lots of Snap Strips using only the product labeling written in English.

Within 5 minutes, a technician collected a second capillary finger sample for comparison on the YSI analyzer. The glucose concentrations of the samples tested ranged from 56 to 362 mg/dL as measured on the reference. The lay user results with the EON L system compared to YSI are summarized below:

for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
10/14 (71.4%)	14/14 (100%)	14/14 (100%)

for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/136 (73.5%)	133/136 (97.8%)	136/136 (100%)	136/136 (100%)

Regression analysis results for lay user EON L vs YSI:
$Y = 0.982x + 1.28$, $R^2 = 0.996$

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The labeling states that the expected glucose range for non-diabetic, non-pregnant fasting adults to be <100 mg/dL, and two hours after meals, the levels should be less than 140 mg/dL.

   American Diabetes Association: Standard of Medical Care in Diabetes 2014, Diabetes Care, vol.38, Supplement 1, S8-S16. January 2015.

N. Instrument Name:

Joinsoon EON L blood glucose meter

O. System Descriptions:

1. Modes of Operation:

   This systems have two types of test strips as described in the device description above. Each test strip requires a sample volume of 0.8 uL.

   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 these devices. Samples are applied directly to the test strips as they are collected.

4. Specimen Sampling and Handling:
   The glucose tests are intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strips by capillary action.

5. Calibration:
   There is no calibration required by the user for the Joinsoon EON L or Joinsoon EON LS blood glucose meters. The meters are automatically coded.

6. Quality Control:
   Glucose control solutions at 3 different concentrations (Level 1, Level 2, and Level 3 are available; Level 2 is included) 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 vial labels. 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:

The sponsor performed a sample volume study to verify the minimum sample volume requirement for the EON L and EON LS systems using blood samples at 2 glucose concentrations (48 and 150 mg/dL) and samples volumes ranging from 0.2 – 0.9 µL (0.2 µL, 0.3 µL, 0.4 µL, 0.5 µL, 0.6 µL, 0.7 µL, 0.8 µL, 0.9 µL and 1.0 µL). Results support the claimed sample volume of 0.8 µL. Validation testing demonstrated that the sample detection feature functioned appropriately when the sample volume was <0.8uL.

2. **Altitude Study:**

   To evaluate the effects of altitude, the Joinsson EON L blood glucose meters were evaluated with 3 Single Strip lots and 3 Snap Strip lots tested on 6 meters using 3 whole blood samples each spiked to 3 glucose concentrations (77, 168, 285 mg/dL). The samples were tested at 2256, 4118, 7951, 9500 and 10,745 feet above sea level. Results obtained were compared with those obtained by YSI. The results demonstrate acceptable bias to the reference to support the claims in the labeling that altitudes up to 10,745 feet have no significant effect on blood glucose measurements from the Joinsoon EON L and EON LS Glucose Monitoring Systems.

3. **Hematocrit Study:**

   The effect of different hematocrit levels on the EON L and EON LS systems was evaluated using venous whole blood samples with hematocrit levels of 30 - 55% (30, 35, 40, 45, 50, and 55%) spiked with glucose to achieve target concentrations of 77, 167, and 286 mg/dL. Results of samples at each hematocrit level were compared to the corresponding YSI value as well as to 40% Hct levels. Three Single and three Snap Strip test strip lots were used in the study. The % bias of the Joinsoon EON L and EON LS system results relative to YSI demonstrated adequate performance to support the claimed hematocrit range of 30-55%.

4. **Test System operating conditions:**

   Temperature and humidity operating conditions were evaluated on the EON L and EON LS systems for temperatures ranging from 50°F-104°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 conditions of 50°F-104°F (10°C -40°C) 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 on average at the 8th grade level.

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, Barbicide Wipes Disinfecting Towelettes (EPA Registration # 46781-8-954). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 2000 cleanings and 2000 disinfection steps with the Barbicide Wipes Disinfecting Towelettes. The robustness studies were designed to simulate 3 years of single-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.