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

A. 510(k) Number:

k162564

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood from the fingertip, forearm, and palm.

D. Type of Test:

Quantitative amperometric assay (FAD-glucose dehydrogenase)

E. Applicant:

Tianjin Empecs Medical Device Co., Ltd.

F. Proprietary and Established Names:

Medisign GH81 Blood Glucose Monitoring System
Medisign GH82 Blood Glucose Monitoring System
Medisign GH83 Blood Glucose Monitoring System

Medisign GH81 BT Blood Glucose Monitoring System
Medisign GH82 BT Blood Glucose Monitoring System
Medisign GH83 BT Blood Glucose Monitoring System

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

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   Medisign GH81 Blood Glucose Monitoring System
   The Medisign GH81 Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

   The Medisign GH81 Blood Glucose Monitoring System is comprised of the Medisign GH81 Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

   Medisign GH81 BT Blood Glucose Monitoring System
   The Medisign GH81 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

   The Medisign GH81 BT Blood Glucose Monitoring System is comprised of the Medisign GH81 Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

   Medisign GH82 Blood Glucose Monitoring System
   The Medisign GH82 Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm

and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH82 Blood Glucose Monitoring System is comprised of the Medisign GH82 Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

Medisign GH82 BT Blood Glucose Monitoring System
The Medisign GH82 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH82 BT Blood Glucose Monitoring System is comprised of the Medisign GH82 BT Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

Medisign GH83 Blood Glucose Monitoring System
The Medisign GH83 Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH83 Blood Glucose Monitoring System is comprised of the Medisign GH83 Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

Medisign GH83 BT Blood Glucose Monitoring System
The Medisign GH83 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH83 BT Blood Glucose Monitoring System is comprised of the Medisign GH82 BT Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

3. Special conditions for use statement(s):
   - This system is only for in vitro diagnostics use and for self-testing.
   - This system is for over-the counter use, for single-patient use only.
   - This system is not designed for use with arterial, venous, serum or plasma samples.
   - This system is not designed for use with neonatal.
   - This system is not for screening or diagnosis of diabetes mellitus.
   - Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).
   - Testing outside of HCT level range of (20~60%) and recommended storage conditions (add the conditions) may cause inaccurate results.
   - Inaccurate results may occur if used at altitudes above 11,480 feet.
   - This system is not for the use on patients in shock, dehydrated patients
   - Inaccurate results may occur in severely hypotensive individuals
   - Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
   - This system is not for use on critically ill patients.
   - Alternative site measurements should never be used to calibrate continuous glucose monitoring (CGMs).
   - Alternative site measurements should never be used for insulin dosing calculations.

4. Special instrument requirements:
   Medisign GH81 Blood Glucose meter
   Medisign GH82 Blood Glucose meter
   Medisign GH83 Blood Glucose meter

   Medisign GH81 BT Blood Glucose meter
   Medisign GH82 BT Blood Glucose meter
   Medisign GH83 BT Blood Glucose meter

I. Device Description:

The Medisign GH81, GH82, GH83, GH81 BT, GH82 BT, GH83 BT Blood Glucose Monitoring Systems are comprised of a blood glucose meter, blood glucose test strips, Medisign GH Glucose control solutions (Level 2, Level 3), lancing device, sterile lancets, and a carrying case. The blood glucose test strips, blood glucose control solutions, lancing device, sterile lancets and data transporting cable are sold separately. The Medisign GH81, GH82, GH83 Blood Glucose Monitoring System allows transmission of blood glucose test results to a personal computer (PC) via an external USB cable (available for purchase separately) and Medisign GH81 BT, GH82 BT, GH83 BT Blood Glucose Monitoring System can transmit blood glucose test results to a PC via an external USB cable or a Bluetooth Low Energy transmitter.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   OneTouch Verio Flex Blood Glucose Monitoring System

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

   k150214

3. Comparison with predicate:

Similarities			
Features	**Predicate Device OneTouch Verio Flex Blood Glucose Monitoring System (k150214)**	**Candidate Device Medisign GH81, GH82, GH83**	**Candidate Device Medisign GH81 BT, GH82 BT, GH83 BT**
Intended Use	The OneTouch Verio Flex™ 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 fingertip. The OneTouch Verio Flex™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared OneTouch Verio Flex™ 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 OneTouch Verio Flex™ Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes, or	Same	

Similarities			
Features	**Predicate Device OneTouch Verio Flex Blood Glucose Monitoring System (k150214)**	**Candidate Device Medisign GH81, GH82, GH83**	**Candidate Device Medisign GH81 BT, GH82 BT, GH83 BT**
Enzyme	FAD-GDH	Same	
Test Principle	Amperometry	Same	
Test Sample	Capillary whole blood	Same	
Operating Temperature	50 – 104ºF	Same	
Operating Humidity	10 – 90%RH	Same	
Hematocrit Range	20-60%	Same	
Measuring Range	20 - 600 mg/dL	Same	
Memory Capacity	500 test result	Same	

Differences			
Features	**Predicate Device (k150214) OneTouch Verio Flex Blood Glucose Monitoring System**	**Candidate Device Medisign GH81, GH82, GH83**	**Candidate Device Medisign GH81 BT, GH82 BT, GH83 BT**
Measuring Time	5 seconds	6 seconds	
Coding of Test Strip	No-Coding	Auto coding	

Differences			
Features	**Predicate Device (k150214) OneTouch Verio Flex Blood Glucose Monitoring System**	**Candidate Device Medisign GH81, GH82, GH83**	**Candidate Device Medisign GH81 BT, GH82 BT, GH83 BT**
Sample Volume	0.4 µL	0.5 µL	
Averaging Results	7, 14, 30 and 90 days	7, 14 and 30 days	
Alternative Site	Not Available	Palm and forearm	
Pre/Post-meal flagging	Not available	Available	
Data Download	USB or Bluetooth Low Energy	USB	USB and Bluetooth Low Energy

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

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).

CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2005).

IEC60601-1-2 Edition 4.0, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)), 2014.

L. Test Principle:

The Medisign GH81, GH82, GH83, GH81 BT, GH82 BT and GH83 BT Blood Glucose Monitoring Systems quantitatively measure the glucose in a whole blood sample by detecting electrical current that results from a chemical reaction of glucose in the blood with the Flavin adenine dinucleotide-Glucose dehydrogenase enzyme (FAD-GDH) on the test strip. The electrical current is proportionally to the amount of glucose in the blood sample; it is measured by the meter and is converted to a blood glucose value for display to the user.

Glucose measurements from this system are reported as plasma equivalents.

M. Performance Characteristics (if/when applicable):

The six systems in this submission are identical except for the presence or absence of blue tooth functionality, case color and name; therefore, performance data provided in this section is applicable to all six systems.

a. Precision/Reproducibility:

Within-run precision (repeatability) was assessed using venous blood from one donor adjusted with glucose to 5 glucose levels: 30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL. These samples were tested using three lots of test strips and 10 meters. Each sample was tested in 10 replicates per meter and per strip lot, giving a total of 100 measurements/lot (n=100) and 300 measurements per glucose level. Results are summarized below:

Glucose Concentration (mg/dL)	Strip lot	n	Mean (mg/dL)	SD (mg/dL)	% CV
30- 50	1	100	41	2.5	3.8
	2	100	41	1.5	3.7
	3	100	41	1.4	3.4
51-110	1	100	87	2.8	3.2
	2	100	87	3.1	3.6
	3	100	87	2.7	3.2
111-150	1	100	131	2.5	1.9
	2	100	132	2.9	2.2
	3	100	131	2.8	2.1
151-250	1	100	211	4.8	2.3
	2	100	211	5.0	2.4
	3	100	211	5.1	2.4
251-400	1	100	331	7.1	2.1
	2	100	333	7.4	2.2
	3	100	332	7.2	2.2

Intermediate precision:

Intermediate (between day) precision was evaluated using 3 lots of test strips and 10 meters. Glucose control solutions in three concentration ranges were used (60-80 mg/dL, 96-114 mg/dL and 280-420 mg/dL). Each sample was tested over 10 days with each meter, for each test strip lot, resulting in a total of 100 measurements per lot and 300 measurements per glucose level. Results are summarized below:

Glucose Concentration (mg/dL)	Strip lot	n	Mean (mg/dL)	SD (mg/dL)	% CV
30-50	1	100	41	2.0	4.9
	2	100	42	2.0	4.9
	3	100	41	1.8	4.3
96-144	1	100	120	2.9	2.4
	2	100	122	2.8	2.3
	3	100	120	3.0	2.5
280-420	1	100	350	7.2	2.1
	2	100	353	7.8	2.2
	3	100	350	7.8	2.2

b. *Linearity/assay reportable range:*

Linearity testing was performed using venous whole blood adjusted to 9 different glucose concentrations ranging from 18-610 mg/dL (18, 42, 65, 103, 147, 205, 359, 512, and 603 mg/dL). Each concentration was tested in 20 replicates using the candidate meter and the values compared to measurements made with a laboratory method (YSI 2300 analyzer). The evaluation yielded the following regression equation:

$$y = 1.0079x + 4.3865, R^2 = 0.9979$$

The results of the study support the claimed glucose measurement range of 20 to 600 mg/dL. If a sample result is less than 20 mg/dL the result is flagged by the meter as "LO" and if a sample result exceeds 600 mg/dL the result is flagged by the meter as "HI". The LO and HI features were tested and were demonstrated to function as intended.

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

Traceability

The systems are traceable to NIST standard reference material 917c, dry D-Glucose (Dextrose).

Test strips stability:

The test strips are available in vials and individually wrapped in foil.

Test strip vial stability was assessed in accelerated and real-time studies. The testing protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims vial shelf life stability of 26 months and open-vial stability of 3 months when stored at 39.2 to 86°F (4-30°C) and relative humidity (RH) of 10-90%.

Closed vial stability and aluminum foil pack:
Test strip shelf-life stability for the individually wrapped test strips was assessed in accelerated and real-time studies. The testing protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims shelf life stability of 26 months for the individually wrapped strips when stored at 39.2 to 86°F (4-30°C) and 10-90% RH.

d. Detection limit:

The reportable range is 20-600 mg/dL. This range was verified by the linearity study (M.1.b above).

e. Analytical specificity:

Interference studies were performed to assess 26 endogenous and exogenous substances. Blood samples were spiked to obtain two levels of glucose concentrations: level 1 (50-100 mg/dL) and level 2 (250-350 mg/dL). Samples were tested in 10 replicates on each of 3 strip lots and compared to an established laboratory method (YSI 2300 glucose analyzer).

The substances tested and the highest concentration tested with no significant interference are summarized in the below table:

Interference substance	Highest tested concentration with no significant interference
Acetaminophen	20 mg/dL
Ascorbic acid	3 mg/dL
Bilirubin	25 mg/dL
Caffeine	10 mg/dL
Cholesterol	500 mg/dL
Creatinine	10 mg/dL
Dopamine	4 mg/dL
EDTA	200 mg/dL
Ephedrine	1 mg/dL
Galactose	10 mg/dL
Glutathione	3.0732 mg/dL
Gentisic Acid	30 mg/dL
Hemoglobin	20,000 mg/dL

Interference substance	Highest tested concentration with no significant interference
Heparin	500 IU/mL
Ibuprofen	50 mg/dL
L-Dopa	0.5 mg/dL
Maltose	10,000 mg/dL
Methyl Dopa	3 mg/dL
Salicylate	50 mg/dL
Tolbutamide	100 mg/dL
Tolazamide	40 mg/dL
Triglycerides	1500 mg/dL
Uric acid	10 mg/dL
Pyruvic acid	4 mg/dL
Tetracycline	10 mg/dL
Xylose	10 mg/dL

Based on these results the sponsor included the following information in their labeling:

If you have certain conditions that may cause your blood level of uric acid to rise, such as gout or kidney disease (>10 mg/dL uric acid) then your blood glucose results may be inaccurate. If you are unsure, then ask your doctor.

If you are taking acetaminophen containing drugs (e.g. Tylenol, certain cold and flu remedies etc.) in excess of the recommended levels (>20 mg/dL) then you may get inaccurate results with this system. If you are unsure, then ask your doctor.

If you are taking vitamin C (ascorbic acid) in excess of the recommended levels >3 mg/dL, then your glucose results may be inaccurate with this system. If you are unsure, then ask your doctor.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

To assess the performance of the Medisign GH81 BT Blood Glucose Monitoring System (representative of all six candidate test systems) in the hands of the intended users, a study was performed at one clinical site using three test strip lots with 159 untrained lay user participants that obtained their own fingerstick sample and 102 participants that obtained their own palm and forearm samples. Each subject performed testing on their own sample and results were compared to those obtained by a health care professional on the YSI 2300. The range of glucose values for the samples as measured by YSI was 38 to 357 mg/dL. The results relative to the YSI are summarized below:

Summary of Fingertip vs. YSI

Accuracy for blood glucose levels <75 mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
12/12 (100%)	12/12 (100%)	12/12 (100%)	
Accuracy for blood glucose levels ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15 %	Within ± 20%
85/147 (57.8%)	137/147 (93.2%)	147/147(100%)	147/147 (100%)

Summary of Palm vs. YSI

Accuracy for blood glucose levels <75mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
2/4 (50.0 %)	4/4 (100 %)	4/4 (100 %)	
Accuracy for blood glucose levels ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15 %	Within ± 20%
65/98 (66.3 %)	93/98 (94.9 %)	98/98 (100 %)	98/98 (100 %)

Summary of Forearm vs. YSI

Accuracy for blood glucose levels <75mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
4/4 (100 %)	4/4 (100 %)	4/4 (100 %)	
Accuracy for blood glucose levels ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15 %	Within ± 20%
61/98 (62.2 %)	95/98 (96.9 %)	98/98 (100 %)	98/98 (100 %)

Linear Regression:

Site	Slope	Intercept	R^2	N	Glucose range (mg/dL)
Fingertip	1.021	-1.562	0.980	159	38-357
Palm	0.982	3.4418	0.986	102	39-368
Forearm	0.971	4.2455	0.986	102	39-367

Prior to the lay-user study the readability of the labeling was assessed using a Flesch-Kincaid analysis and was found to be written at the 8th grade level.

During the lay user study described in Section M.3.c, the participants were asked to complete a questionnaire to evaluate the usability of the use of the device and the clarity of user manual. Overall, the users indicated that they could successfully conduct the test.

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):

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

   The labeling includes the following expected glucose values for people without diabetes:
   Before a meal (fasting): <100 mg/dL
   2 h after a meal: < 140mg/dL.

   These ranges were cited from the American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 31:S55-S60, 2016.

N. Instrument Name:

Medisign GH81 Blood Glucose meter
Medisign GH82 Blood Glucose meter
Medisign GH83 Blood Glucose meter

Medisign GH81 BT Blood Glucose meter

Medisign GH82 BT Blood Glucose meter
Medisign GH83 BT Blood Glucose meter

O. System Descriptions:

1. Modes of Operation:

   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 __ X_____ or No _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____ X ____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the fingertip, palm, and forearm which are applied directly to the test strip by capillary action as they are collected.

5. Calibration:

   The meter does not require calibration or coding by the user. The labeling includes instructions for the user to verify that the code number on the test strip vial matches the code number displayed on the meter once the test strip is inserted.

6. Quality Control:
   Two levels of controls are available for use with this meter. The control solutions are purchased separately using the contact information provided in the labeling. The labeling includes instructions for the user to 'press the '<' or '>' button on the meter to mark the result as a control solution result to distinguish them from blood glucose results in the

meter memory. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. **Sample volume study**:

   The sponsor performed a study to verify the test strip sample volume requirement for the Medisign GH81 BT Blood Glucose Monitoring System (representative of the six candidate test systems). Blood samples were testes at 5 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 sample volume of 0.5 µL. Er4 was validated for "not enough blood sample" and was demonstrated to function as intended.

2. **Altitude Study:**

   To evaluate the effects of altitude on the Medisign GH81 BT Blood Glucose Monitoring System (representative of the six candidate test systems), venous blood samples were altered to 5 glucose concentrations intervals (81-83, 121-124, 245-251, 376-380, and 488-493 mg/dL) and tested at conditions to simulate 11,480 feet above sea level. Results obtained were compared with those obtained with the comparator method (YSI). The results demonstrate acceptable bias to the reference to support the claims in the labeling at altitudes up to 11,480 feet have no significant effect on blood glucose measurements

3. **Hematocrit Study:**

   The effect of different hematocrit levels on the Medisign GH81 BT Blood Glucose Monitoring System (representative of the six candidate test systems) was evaluated using venous whole blood samples with hematocrit levels of 19-61% (19, 30, 42, 50, 61%) at 3 concentrations of glucose (40 mg/dL, 120 mg/dL, and 350 mg/dL). Three test strips lots were evaluated with 10 meters. Each sample was tested in 10 replicates for each hematocrit level and glucose levels. Results of samples at each hematocrit level were compared to samples with the same concentration at 42% hematocrit as well as to the corresponding YSI value. The % bias of the Medisign GH81 BT Blood Glucose meter results relative to YSI demonstrated adequate performance to support the claimed hematocrit range of 20-60%.

4. **Test System Operating Conditions:**

   Operating conditions studies were performed using a single test strip lot and three meters, with venous blood altered to glucose concentrations of 41 mg/dL, 123 mg/dL and 345 mg/dL. Testing with the Medisign GH81 BT Blood Glucose Monitoring System (representative of the six candidate test systems) was performed at the combination of extremes of claimed temperature and humidity operating conditions and results compared

to an established laboratory method (YSI). Results support the claims in the labeling that the test system can be used at temperatures from 50° to 104°F (10-40°C) and relative humidities of 10-90%.

5. **EMC Testing:**

   The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed and the device system was found compliant.

6. **Infection Control Studies:**

   The six systems in this submission are identical except for the presence or absence of blue tooth functionality, case color and name; therefore, infection control studies is applicable to non-BT meters Medisign GH81, Medisign GH82 and Medisign GH83 glucose meters.

   The device system is intended for single-patient use. Disinfection efficacy studies were performed on the materials comprising the Medisign GH81 BT, Medisign GH82 BT and Medisign GH83 BT glucose meters by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes® disinfecting towelettes (EPA registration #46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meters after 11,000 cleaning and 11,000 disinfection cycles. The robustness studies support 3 years of single-patient use and multi-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to the finalization of the guidance documents.

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.