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

I Background Information:

A 510(k) Number

K252749

B Applicant

Shanghai Medconn Medical Technology Co., Ltd.

C Proprietary and Established Names

Medconn 8K Glycated Hemoglobin Test System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PDJ	Class II	21 CFR 862.1373 - Hemoglobin A1c Test System	CH - Clinical Chemistry
LCP	Class II	21 CFR 864.7470 - Glycosylated hemoglobin assay	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Whole Blood Glycosylated Hemoglobin (HbA1c)

C Type of Test:

Quantitative Ion exchange High Performance Liquid Chromatography (HPLC)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Medconn 8K Glycated Hemoglobin Test System is intended for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human whole blood or hemolysate with ion-exchange high performance liquid chromatography (HPLC) using the Medconn 8K HbA1c Assay Kit (HPLC) on the Medconn 8K Glycated Hemoglobin Analyzer, models MQ-8000 and MQ-8000PT.

Hemoglobin A1c measurements are used as an aid in diagnosis of diabetes, as an aid to identify patients who may be at risk for developing diabetes mellitus, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

- The device should not be used in newborns, pregnant patients, patients with heterozygous sickle cell trait, hemolytic diseases and recent significant or chronic blood loss.
- The device should not be used in patients during pregnancy for diagnosis of gestational diabetes.
- In cases of rapidly evolving type 1 diabetes the increase of HbA1c values might be delayed compared to the acute increase in glucose concentrations. In these conditions diabetes mellitus must be diagnosed based on plasma glucose concentration and/or the typical clinical symptoms.
- The device should not be used to diagnose or monitor patients with conditions that alter the life span of the red blood cells, such as: iron deficiency and hemolytic anemia, various hemoglobinopathies, thalassemia, hereditary spherocytosis, malignancies and severe chronic hepatic and renal disease polycythemia or post-splenectomy . For example samples of patients with hemolytic anemia may present a decreased value of HbA1c due to a shortened life span of their red blood cells. The magnitude of this effect depends on the severity of the anemia. Samples of patients with polycythemia or post-splenectomy patients may present an increased value of HbA1c due to the relatively long life span of their red blood cells.

D Special Instrument Requirements:

The Medconn 8K Glycated Hemoglobin Analyzer

IV Device/System Characteristics:

A Device Description:

The Medconn 8K Glycated Hemoglobin Test System consists of the following components:

- The Medconn 8K Glycated Hemoglobin Analyzer; models MQ-8000 and MQ-8000PT: automated instrument for running the Medconn 8K HbA1c Assay (HPLC) to measure the content of HbA1c in human whole blood. These analyzers are identical except the sample disc cover colors. The color for model MQ-8000 analyzer is blue, and the color for the MQ-8000PT is black.
- The Medconn 8K HbA1c Assay Kit (HPLC): distributed with 200-test to 10,000-test packages that contains HbA1c reagents A, B, C. These reagents are succinate buffers with different ionic strengths used for elution of different substances in HPLC.
- The Medconn Hemoglobin A1c Calibrator: lyophilized powers containing hemoglobin, 1 vial of Calibrator Level 1 (20 uL), and 1 vial of Calibrator Level 2 (20 uL).
- The Medconn Hemoglobin A1c Control (2 levels): lyophilized powders containing hemoglobin, which are reconstituted with labeled volume of distilled water or are directly reconstituted into diluted samples using haemolyser.
- The Medconn HbA1c Haemolyser (reagent H): used for pretreatment of blood for HbA1c testing, containing deionized water, a surfactant, and less than 0.05% of sodium azide as a preservative.
- The Medconn 8K HbA1c Column Kit (HPLC): assembled HPLC columns filled with hydrophilic polymer for use with the Medconn MQ-8000 and MQ-8000PT Glycated Hemoglobin Analyzers.

B Principle of Operation:

The device is based on the principle of chromatographic separation of HbA1c in high performance liquid chromatography (HPLC). A high-pressure pumping system delivers a buffer solution to an analytical cartridge and detector. The analyzer has two modes: whole blood mode and manually hemolyzed and pre-diluted sample mode. Whole blood samples undergo an automatic hemolysis and dilution process before being introduced into the analytical flow path. The manually hemolyzed and pre-diluted samples loaded in sample cups at a designated location are directly introduced for analysis.

A programmed buffer gradient of increasing ionic strength delivers the sample to the analytical cartridge where the hemoglobin species are separated based upon their ionic interactions with the cartridge material and the buffer gradient. The separated hemoglobin species then pass through the flow cell where changes in the absorbance are measured at 415nm and recorded as a digital chromatogram.

The software performs an analysis of the hemoglobin peaks in the chromatogram, recording information including retention time, peak area, and relative peak area of the detected substance over the total peak area of all substances. Peaks identified as target analytes are calibrated to generate a report and a chromatogram for each sample.

C Instrument Description Information:

1. Instrument Name:

   Medconn 8K Glycated Hemoglobin Analyzer; models MQ-8000 and MQ-8000PT

2. Specimen Identification:

Sample identification is via barcoding or manual entry.

3. Specimen Sampling and Handling:

   Venous whole blood samples collected in K2-EDTA can be stored at 2-8°C for 5 days and at -20°C for 30 days.

   Hemolysate should be stored at 2-8°C for less than 8 hours.

4. Calibration:

   Calibration, using the Medconn Hemoglobin A1c Calibrators, should be performed once following the use of a new batch of the Medconn 8K HbA1c assay kit, the installation of a new chromatographic column, instrument repair, maintenance, or replacement of key components. Additional calibration may be performed at the discretion of the laboratory.

5. Quality Control:

   Quality control of the Medconn 8K Glycated Hemoglobin Test System can be conducted using the Medconn Hemoglobin A1c Controls (2 levels). The labeling for the device includes quality control recommendations and instructions.

V Substantial Equivalence Information:

A Predicate Device Name(s):

D-100 HbA1c, D-100 HbA1c Calibrator Pack

B Predicate 510(k) Number(s):

K151321

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252749	K151321
Device Trade Name	Medconn 8K Glycated Hemoglobin Test System	D-100 HbA1c
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the quantitative determination of hemoglobin A1c in human whole blood as an aid in diagnosis of diabetes, as an aid to identify patients who may be at risk for developing diabetes mellitus, and for the monitoring of long-term	Same

	blood glucose control in individuals with diabetes mellitus.	
Test principle	Ion exchange HPLC	Same
Sample Types	Human whole blood and hemolysate	Same
Standardization/ Traceability	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP)	Same
General Device Characteristic Differences		
Matrices	K2-EDTA	K2-EDTA, K3-EDTA Potassium Oxalate/ Sodium Fluoride, Sodium Citrate, Sodium Heparin, Lithium Heparin
Measuring range	3.0% to 17.0% (NGSP); 9.3 - 162.3 mmol/mol HbA1c (IFCC)	3.5 to 20% (NSGP); 15 – 195 mmol/mol HbA1c (IFCC)

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3 (Reaffirmed: September 2019): Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- CLSI EP06 2nd Edition: Evaluation of the Linearity of Quantitative Measurement Procedures
- CLSI EP07 3rd Edition: Interference Testing in Clinical Chemistry
- CLSI EP09c 3rd Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples
- CLSI EP25-A (Replaces EP25-P): Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline
- IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)]
- IEC 61326-1 Edition 3.0 2020-10: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- IEC 61326-2-6 Edition 3.0 2020-10: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- IEC 81001-5-1 Edition 1.0 2021-12: Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle
- AAMI TIR69:2017/(R2020): Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems
- IEEE ANSI USEMCSC C63.27-2021: American National Standard for Evaluation of Wireless Coexistence

- ISO 17511 Second edition 2020-04: In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

VII Performance Characteristics (if/when applicable):

1. Analytical Performance:

Since the analyzer models are functionally identical and only differ in sample disc colors, the Medconn 8K Glycated Hemoglobin Analyzer model MQ-8000 was used as the representative model for the studies described below to support both analyzer models.

1. Precision/Reproducibility:

Precision studies were conducted with the Medconn 8K Glycated Hemoglobin Test System using four K2-EDTA venous whole blood samples at concentrations near 5%, 6.5%, 8%, and 12% HbA1c (S1, S2, S3, and S4 respectively) and two quality control samples at concentrations near 6% and 11% HbA1c (QC1 and QC2 respectively). Samples were either analyzed as whole blood samples or as manually prepared hemolysate samples. Samples were analyzed on three Medconn 8K Glycated Hemoglobin Analyzer instruments with three lots of reagents in duplicates per run, two runs per day, for 20 days. For each sample there were 720 measurements. Results in NGSP and IFCC units are shown in the tables below.

All Analyzers Combined, Whole Blood, % HbA1c (NGSP) units

Sample	Mean Values (%)	%CV, Percent CV for All Analyzers Combined					
		Repeatability	Between-Run	Between-Day	Between-Lot	Between-Analyzer	Total
S1	5.13	0.89	0.18	0.06	0.06	0.00	0.91
S2	6.70	0.83	0.25	0.00	0.09	0.00	0.87
S3	8.01	0.71	0.26	0.11	0.00	0.00	0.76
S4	12.16	0.62	0.17	0.17	0.07	0.00	0.66
QC1	5.50	1.17	0.23	0.00	0.12	0.09	1.20
QC2	11.06	0.70	0.03	0.14	0.02	0.01	0.72

Note: Negative variance component values have been set to zero

All Analyzers Combined, Whole Blood, mmol/mol (IFCC) units

Sample	Mean Values mmol/mol	%CV, Percent CV for All Analyzers Combined					
		Repeatability	Between-Run	Between-Day	Between-Lot	Between-Analyzer	Total
S1	32.52	1.17	0.35	0.00	0.00	0.09	1.21
S2	49.72	0.92	0.25	0.20	0.00	0.00	0.97
S3	63.96	0.72	0.31	0.11	0.06	0.00	0.79
S4	109.34	0.69	0.11	0.20	0.08	0.00	0.73
QC1	36.56	1.44	0.42	0.00	0.07	0.13	1.49
QC2	97.37	0.81	0.10	0.17	0.06	0.00	0.83

Note: Negative variance component values have been set to zero

All Analyzers Combined, Hemolysate, % HbA1c (NGSP) units

Sample	Mean Values (%)	%CV, Percent CV for All Analyzers Combined					
		Repeatability	Between-Run	Between-Day	Between-Lot	Between-Analyzer	Total
S1	5.15	0.95	0.07	0.18	0.00	0.05	0.97
S2	6.41	0.89	0.00	0.00	0.15	0.00	0.86
S3	7.91	0.75	0.19	0.06	0.02	0.00	0.78
S4	12.05	0.70	0.16	0.05	0.07	0.00	0.73
QC1	5.50	1.10	0.26	0.21	0.23	0.00	1.17
QC2	11.07	0.67	0.24	0.10	0.00	0.05	0.71

Note: Negative variance component values have been set to zero

All Analyzers Combined, Hemolysate, mmol/mol (IFCC) units

Sample	Mean Values mmol/mol	%CV, Percent CV for All Analyzers Combined					
		Repeatability	Between-Run	Between-Day	Between-Lot	Between-Analyzer	Total
S1	32.67	1.22	0.00	0.20	0.01	0.05	1.23
S2	46.50	1.02	0.16	0.00	0.14	0.00	1.03
S3	62.91	0.78	0.17	0.13	0.00	0.00	0.80
S4	108.17	0.73	0.17	0.08	0.09	0.01	0.76
QC1	36.58	1.39	0.40	0.32	0.29	0.00	1.49
QC2	97.40	0.77	0.18	0.18	0.03	0.05	0.81

Note: Negative variance component values have been set to zero

2. Linearity:

Linearity was evaluated for the Medconn 8K Glycated Hemoglobin Test System with three lots of reagents using a dilution series consisting of 11 levels of HbA1c prepared by mixing high and low K2-EDTA whole blood pools. The expected sample concentrations were 3.1%, 4.5%, 5.9%, 7.3%, 8.7%, 10.1%, 11.5%, 12.9%, 14.3%, 15.7%, and 17.1% HbA1c. The samples were either analyzed as whole blood samples or were manually hemolyzed before analyzing. Three replicates were tested at each concentration. The measured mean values were compared to the expected values. The linear regressions for the three lots of reagents are the following:

Whole Blood

NGSP unit:

1st lot of reagent: Y=0.9913X + 0.0056, R2=0.9999
2nd lot of reagent: Y=0.9946X - 0.0393, R2=0.9999
3rd lot of reagent: Y=0.9922X - 0.0031, R2=0.9999

IFCC unit:

1st lot of reagent: Y=0.9913X - 0.1420, R2=0.9999
2nd lot of reagent: Y=0.9946X - 0.5566, R2=0.9999
3rd lot of reagent: Y=0.9922X - 0.2172, R2=0.9999

Hemolysate

NGSP unit:

1st lot of reagent: Y=0.9935X - 0.0374, R2=0.9999
2nd lot of reagent: Y=0.9916X - 0.0208, R2=0.9999
3rd lot of reagent: Y=0.9924X - 0.0295, R2=0.9999

IFCC unit:

1st lot of reagent: Y=0.9935X - 0.5619, R2=0.9999
2nd lot of reagent: Y=0.9916X - 0.4257, R2=0.9999
3rd lot of reagent: Y=0.9924X - 0.5010, R2=0.9999

Results of the linearity study support the claimed measuring range of the device of 3.0% to 17% HbA1c (9.3-162.3 mmol/mol).

3. Analytical Specificity/Interference:

Interference studies were performed to assess the impact of endogenous substances on the performance of the Medconn 8K Glycated Hemoglobin Test System. Pooled K2-EDTA venous whole blood at two HbA1c levels (~6.5 and ~8.0% HbA1c) spiked with potential interferent was analyzed in replicates of two and compared to the same whole blood pool without interferent (control). The highest concentrations at which no significant interference (a difference of no more than ±6% from the control sample as defined by the sponsor) was observed are summarized below:

Endogenous Substances

Interferent	Highest Concentration Level Tested with No Significant Interference (mg/dL)
Unconjugated Bilirubin	21.3
Conjugated Bilirubin	19.2
Rheumatoid Factors	750 IU/mL
Total Protein	21g/dL
Glucose	2,000
Triglycerides	6,000

Exogenous Substances

Interferent	Highest Concentration Level Tested with No Significant Interference (mg/dL)
Acetaldehyde	60
Acetaminophen	200
Acetylcysteine	166
Ampicillin-Na	1,000
Ascorbic acid	100
Cefoxitin	2,500
Cyclosporine	5
Doxycyclin	50
Heparin	5,000 U/L
Ibuprofen	500
Levodopa	20
Methyldopa	20

Interferent	Highest Concentration Level Tested with No Significant Interference (mg/dL)
Metronidazole	200
Phenylbutazone	400
Rifampicin	64
Theophylline	100

Cross Reactivity with Hemoglobin Derivatives:

Potential interference from Labile HbA1c, Carbamylated Hb, Acetylated Hb were evaluated. Two HbA1c concentrations of K2-EDTA pooled venous whole blood (~6.5 and ~8.0% HbA1c) were spiked with the prepared potential interferent. The %HbA1c values were compared to the same control sample with no potential interferent present. Significant interference was defined by the sponsor as ≥6% change in HbA1c value of the mean of the test samples relative to the mean of the control samples. The test results and conclusions are as follows:

- Labile A1c - (up to 2000 mg/dL glucose) does not interfere with this assay.
- Carbamylated Hb - (up to 10 mg/dL Potassium cyanate) does not interfere with this assay.
- Acetylated Hb - (up to 1000 mg/dL acetylsalicylic acid) does not interfere with this assay.

Results demonstrated that there was no cross reactivity with these hemoglobin derivatives at tested levels and the labeling states that at physiologically occurring concentrations there is no interference from labile A1c, carbamylated hemoglobin or acetylated hemoglobin.

Hemoglobin Variant Interference:

Hemoglobin variant studies were performed using K2-EDTA venous whole blood samples known to contain hemoglobin variants HbS, HbC, HbD, HbE, HbA2, and HbF. The samples containing the hemoglobin variants were tested using the Medconn 8K Glycated Hemoglobin Test System and comparator methods that have been demonstrated to be free from interference by these hemoglobin variants. The sponsor defined significant interference was as ≥7% change in HbA1c values in the presence of the hemoglobin variants relative to the comparator method. The following tables summarize the tested samples and results:

Hemoglobin Variant Samples Tested in Study #1

Hemoglobin Variant	Number of Samples	Variant Concentration Range (%)	Range of HbA1c Concentration (%)
HbS	25	36 – 42	5.0 – 14.0
HbC	25	30 – 38	5.0 – 10.9
HbD	25	39 – 43	5.3 – 14.7
HbE	25	23 – 27	5.1 – 12.2
HbA2	20	3.5– 5.6	5.2 – 9.0
HbF	23	3.0 – 27	5.5 – 16.5

Hemoglobin Variant Samples Tested in Study #2

Hemoglobin Variant	Number of Samples	Variant Concentration Range (%)	Range of HbA1c Concentration (%)
HbE	10	25.4 – 31.2	5.1 – 10.2
HbF	11	25.6 – 34.5	5.1 – 11.2

Summary of Hemoglobin Variant Test Results for Study #1

Hemoglobin Variant	%Bias, Percent Relative Bias Observed Relative to the Comparator Method			
	~ 6.5 % HbA1c		~ 8.0% HbA1c	
	%Bias	Range of %Bias	%Bias	Range of %Bias
HbS	1.52	0.00 to 3.03	1.81	0.00 to 3.61
HbC	2.31	1.54 to 3.08	1.34	0.00 to 2.67
HbD	0.85	-1.64 to 3.33	-1.83	-2.44 to -1.22
HbE	1.67	-3.17 to 3.33	-0.67	-1.33 to 0.00
HbA2	0.02	-1.49 to 1.52	-0.63	-2.53 to 1.28
HbF	-0.08	-3.33 to 3.08	0.05	-2.44 to 2.53

Summary of Hemoglobin Variant Test Results for Study #2

Hemoglobin Variant	%Bias, Percent Relative Bias Observed Relative to the Comparator Method			
	~ 6.5 % HbA1c		~ 8.0% HbA1c	
	%Bias	Range of %Bias	%Bias	Range of %Bias
HbE	1.19	0.73 to 1.64	1.26	0.63 to 1.89
HbF	0.06	-1.54 to 1.67	0.89	0.00 to 1.78

The results demonstrate no significant interference for HbS, HbC, HbE, HbD, HbA2, and HbF at the concentrations stated in the table above.

4. Assay Reportable Range:

The reportable range for this device is 3.0% – 17.0%% HbA1c (NGSP) or 9.3 – 162.3 mmol/mol HbA1c (IFCC).

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability:
The Medconn 8K Glycated Hemoglobin Test System is traceable to the International Federation of Clinical Chemistry (IFCC) reference calibrators. The assay is certified by the National Glycohemoglobin Standardization Program (NGSP) and IFCC. The NGSP and IFCC certification expires in one year. See the NGSP website for current certification at http://www.NGSP.org.

HbA1c results are provided to users in two different units: NGSP equivalent units (%) and IFCC equivalent units (mmol/mol). These two units are converted using the Master Equation: NGSP (%) = 0.09148 x IFCC (mmol/mol) + 2.152.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   See method comparison study below.

9. Carry-Over:

   A Carryover study was performed and found to be acceptable.

2. Comparison Studies:

1. Method Comparison with Predicate Device:

   Method comparison study was performed using 139 K2-EDTA venous whole blood samples (3.1 to 17.1% HbA1c concentration range) comparing the candidate device results with those from the predicate device (i.e., Bio-Rad D-100 HbA1c Test) performed at NGSP secondary reference laboratories. The study was conducted using both the whole blood and hemolysate modes of the Medconn 8K Glycated Hemoglobin Analyzer. The distribution of samples spanning the measuring interval is as follows:

HbA1c levels, %	# of samples tested	% of sample tested
≤ 5	9	6.5
5.0 – 6.0	15	10.8
6.0 – 6.5	34	24.5
6.5 – 7.0	35	25.2
7.0 – 8.0	18	12.9
8.0 – 9.0	11	7.9
> 9.0	17	12.2
Total	139	100

Regression analyses were performed for the candidate device versus the comparator method. Summary of results are as follows:

Whole blood mode, NGSP unit:

Method	Slope	95% CI	y-intercept	95% CI
Deming	0.9868	0.9617 - 1.0120	0.1619	-0.0062- 0.3300
Passing-Bablok	1.0000	1.0000 - 1.0118	0.1000	0.0106- 0.1000

Hemolysate mode, NGSP unit:

Method	Slope	95% CI	y-intercept	95% CI
Deming	0.9855	0.9645 – 1.0066	0.1589	0.0173 - 0.3004
Passing-Bablok	1.0000	1.0000 - 1.0000	0.1000	0.1000 - 0.1000

Bias Estimation for the whole blood mode:

HbA1c levels (%)	Deming		Passing Boblok	
	Bias (%)	%Bias	Bias (%)	%Bias
5.0	0.0959	1.92	0.1000	2.00
6.5	0.0761	1.17	0.1000	1.54
8.0	0.0563	0.70	0.1000	1.25
12.0	0.0035	0.03	0.1000	0.83

Bias Estimation for the hemolysate mode:

HbA1c levels (%)	Deming		Passing Boblok	
	Bias (%)	%Bias	Bias (%)	%Bias
5.0	0.0864	1.73	0.1000	2.00
6.5	0.0647	0.99	0.1000	1.54
8.0	0.0429	0.54	0.1000	1.25
12.0	-0.0151	-0.13	0.1000	0.83

Total Error calculations and estimation:

The bias estimation values determined in the method comparison study and the precision estimates determined in the precision study were used to determine the total error at each of the HbA1c levels listed in the tables below. Total error was calculated by the following equation: $\%TE = |\%Bias| + 1.96 \times \%CV \times (1 + \%Bias/100)$

Total Error for the whole blood mode:

Regression	HbA1c levels, %	%Bias	%CV	%TE
Deming	5.0	1.92	0.91	3.74
	6.5	1.17	0.87	2.90
	8.0	0.70	0.76	2.20
	12.0	0.03	0.66	1.32
Passing Boblok	5.0	2.00	0.91	3.82
	6.5	1.54	0.87	3.27
	8.0	1.25	0.76	2.76
	12.0	0.83	0.66	2.13

Total Error for the hemolysate mode:

Regression	HbA1c levels, %	%Bias	%CV	%TE
Deming	5.0	1.73	0.97	3.66
	6.5	0.99	0.86	2.69
	8.0	0.54	0.78	2.08
	12.0	-0.13	0.73	1.30
Passing Boblok	5.0	2.00	0.97	3.94
	6.5	1.54	0.86	3.25
	8.0	1.25	0.78	2.80
	12.0	0.83	0.73	2.27

2. Matrix Comparison:

Not applicable. Only K2-EDTA venous whole blood samples are to be used with this device.

3. Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

4. Clinical Cut-Off:

Not applicable.

5. Expected Values/Reference Range:

The sponsor provided the following expected values in their labeling: The following HbA1c ranges recommended by the American Diabetes Association (ADA) may be used as an aid in the diagnosis of diabetes mellitus[1-3]

Hemoglobin A1c		Suggested Diagnosis
NGSP %	IFCC mmol/mol	
≥6.5	≥48	Diabetic
5.7–6.4	39–47	Pre-Diabetic
<5.7	<39	Non-Diabetic

[1]American Diabetes Association. Standards of Medical Care in Diabetes - 2013. Diabetes Care 2013；36 (Suppl.1), S11-66.
[2]World Health Organization. Abbreviated Report of a WHO Consultation: WHO; 2011. Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus.
[3]American Diabetes Association. Standards of Medical Care for Patients with Diabetes Mellitus. Diabetes Care 2002；25 (Suppl.1), S33-49.

6. Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.