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

I Background Information:

A 510(k) Number

K260468

B Applicant

Shenzhen Lifotronic Technology Co., Ltd.

C Proprietary and Established Names

H100Plus Hemoglobin Testing 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:

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:

The H100Plus Hemoglobin Testing System is intended for in vitro quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in venous whole blood and hemolysate from venous whole blood using ion-exchange high performance liquid chromatography (HPLC) on the H100Plus Hemoglobin Analyzer (HPLC).

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

The H100Plus Hemoglobin Testing System is intended for Professional Use Only.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

- For in vitro diagnostic use only.
- HbAlc results must not be used during pregnancy or to diagnose gestational diabetes.
- The product is not intended for testing newborn specimens.
- In rapidly developing type 1 diabetes, an increase in HbAlc may be delayed relative to the acute increase in blood glucose. In such cases, diabetes must be diagnosed based on plasma glucose results and clinical findings rather than HbAlc alone.
- Conditions that alter red blood cell lifespan or turnover may cause HbAlc results that do not accurately reflect average blood glucose. These conditions may include recent significant or chronic blood loss, iron deficiency anemia, hemolytic anemia, hemoglobinopathies, thalassemia, hereditary spherocytosis, malignancy, and severe chronic hepatic or renal disease. HbAlc results from patients with these conditions must not be used alone for the diagnosis of diabetes, identification of individuals at risk of developing diabetes, or assessment of long-term glycemic control. Interpret the results with caution and consider glucose-based testing or other appropriate markers of glycemic control.
- The product is not intended for HbAlc testing in patients with heterozygous sickle cell trait.

D Special Instrument Requirements:

H100Plus Hemoglobin Analyzer(HPLC)

IV Device/System Characteristics:

A Device Description:

The H100Plus Hemoglobin Testing System consists of the following components:

1. H100Plus Hemoglobin Analyzer(HPLC): automated instrument for running the H100Plus HbA1c HPLC assay to measure the content of HbA1c in human whole blood.
2. H100Plus HbA1c Eluents A, B, and C: contain succinate buffer with <0.1% sodium azide as a preservative, used for elution of different substances in HPLC. Eluents A is distributed in 800 mL and 1600 mL packages; Eluent B and C are distributed in 800 mL package only.
3. H100Plus HbA1c Calibrator (2 levels): lyophilized powders containing hemoglobin should be reconstituted with labeled volume of the H100Plus Hemolytic Agent L.
4. H100Plus HbA1c Control Material (2 levels): lyophilized powders containing hemoglobin should be reconstituted with labeled volume of the H100Plus Hemolytic Agent L.
5. H100Plus Hemoglobin Chromatographic Column (HPLC): assembled HPLC columns filled with hydrophilic polymer for use with the H100Plus Hemoglobin Analyzer (HPLC), with 5,000 or 10,000 test capacities.
6. H100Plus Hemolytic Agent L: intended for pre-treatment of human whole blood to lyse red blood cells for releasing glycated and other hemoglobin molecules, can also be used to reconstitute H100Plus HbA1c Calibrator and H100Plus HbA1c Control Material, distributed in 250 mL, 2,500 mL, and 5,000 mL packages.

B Principle of Operation:

The device is based on the principle of ion-exchange high performance liquid chromatography (HPLC) to separate hemoglobin species in a HPLC column. The device uses venous whole blood samples in blood collection tubes (K2 EDTA or K3 EDTA) or manually pre-diluted and hemolyzed venous blood samples in Eppendorf tubes. Whole blood samples are automatically diluted and lysed by the instrument prior to being injected into the column. Pre-diluted (hemolysate) samples are directly injected into the column without the dilution step in the instrument.

A programmed buffer with stepwise eluents containing different salt concentrations delivers the sample into the column. Hemoglobin species are separated through ionic interactions with the column material and are detected at the detection window at wavelengths of 415 nm. The device automatically collects chromatographic data for each hemoglobin fraction and calculates the HbA1c levels based on the peak area ratio.

C Instrument Description Information:

1. Instrument Name:

   H100Plus Hemoglobin Analyzer(HPLC)

2. Specimen Identification:

Sample identification is via barcoding or manual entry.

3. Specimen Sampling and Handling:

   Venous whole blood samples collected in K2-EDTA or in K3-EDTA can be stored at 10-30℃ for up to 24 hours, at 2-8℃ for up to 7 days, or at -80℃ for up to 6 month.

   Manually diluted and hemolyzed samples should be tested immediately.

4. Calibration:

   Calibration using the H100Plus HbA1c Calibrator (2 levels) should be performed:
   - After installation of the analyzer for the first time;
   - After performing maintenance or troubleshooting;
   - After replacing column, filter, or different lots of Eluent;
   - Analyzer is reused after it is shelved for more than 7 days;
   - At least once every 30 days during normal use;
   - At any time when QC is out of range or obvious inaccuracy of analysis results are detected.

5. Quality Control:

   To ensure the reliability of test results, perform quality control testing, using two levels of controls, after powering on the analyzer and prior to daily testing. Additionally, QC should be repeated after any re-calibration. The quality control results shall fall within the established quality control ranges. If results are out of range, instrument status, reagent or calibrator shall be checked for reasons and perform re-calibration if necessary.

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):
D

Device & Predicate Device(s):	K260468	K151321
Device Trade Name	H100Plus Hemoglobin Testing System	D-100 HbA1c, D-100 HbA1c Calibrator Pack

General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for in vitro quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP%) in human whole blood, as an aid in the diagnosis of diabetes mellitus, as an aid to identify patients who may be at risk of developing diabetes mellitus, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus. For Professional Use Only.	Same
Test principle	Ion exchange high performance liquid chromatography (HPLC)	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, K3-EDTA	K2-EDTA, K3-EDTA Potassium Oxalate/ Sodium Fluoride, Sodium Citrate, Sodium Heparin, Lithium Heparin
Measuring range	3.0% to 20.0% (NGSP); 9.3 – 195.1 mmol/mol HbA1c (IFCC)	3.5 to 20% (NSGP); 15 – 195 mmol/mol HbA1c (IFCC)

VI Standards/Guidance Documents Referenced:

- 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 4.0 2025-06, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- 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
- CLSI EP06 2nd Edition, Evaluation of the Linearity of Quantitative Measurement Procedures
- CLSI EP05-A3 (Reaffirmed: September 2019), Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- CLSI EP07 3rd Edition, Interference Testing in Clinical Chemistry
- CLSI EP09c 3rd Edition, Measurement Procedure Comparison and Bias Estimation Using Patient Samples
- CLSI EP25 2nd Edition, Evaluation of Stability of In Vitro Medical Laboratory Test Reagents
- 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

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were conducted with the H100Plus Hemoglobin Testing 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. Precision was evaluated using three H100Plus Hemoglobin Analyzer (HPLC) instruments with three lots of reagents. Samples were analyzed in duplicate per run, two runs per day, for 20 days. For each sample there were 720 measurements. Results in NGSP (%) and IFCC units (mmol/mol) are shown in the tables below for samples diluted and hemolyzed automatically by the analyzer (whole blood) or manually (hemolysate):

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	4.99	0.80	0.00	0.19	0.25	0.82	1.18
S2	6.50	0.59	0.00	0.14	0.29	0.90	1.13
S3	8.02	0.52	0.00	0.15	0.23	0.88	1.06
S4	12.07	0.37	0.00	0.08	0.13	0.90	0.98
QC1	5.12	0.76	0.00	0.25	0.27	0.91	1.24
QC2	10.57	0.39	0.00	0.08	0.14	0.96	1.05

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	31.08	1.41	0.00	0.33	0.43	1.43	2.08
S2	47.50	0.88	0.00	0.21	0.43	1.35	1.68
S3	64.19	0.71	0.00	0.20	0.31	1.20	1.44
S4	108.38	0.45	0.00	0.10	0.16	1.10	1.20
QC1	32.45	1.32	0.00	0.43	0.46	1.56	2.14
QC2	91.98	0.49	0.00	0.10	0.18	1.20	1.32

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	4.99	0.77	0.00	0.16	0.37	0.83	1.21
S2	6.48	0.58	0.00	0.22	0.26	0.93	1.15
S3	8.02	0.50	0.00	0.11	0.18	0.90	1.05
S4	12.03	0.37	0.00	0.13	0.11	0.86	0.95

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	31.00	1.36	0.00	0.28	0.66	1.46	2.12
S2	47.33	0.87	0.00	0.33	0.39	1.38	1.71
S3	64.12	0.69	0.00	0.14	0.25	1.23	1.44
S4	107.97	0.46	0.00	0.16	0.14	1.04	1.16

Note: Negative variance component values have been set to zero

2. Linearity:

Linearity was evaluated for the H100Plus Hemoglobin Testing 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 3.04%, 4.72%, 6.40%, 8.08%, 9.76%, 11.44%, 13.12%, 14.80%, 16.48%, 18.16%, and 19.84% HbA1c. The samples were either analyzed as whole blood samples or were manually hemolyzed before analyzing. Five 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=0.9976X - 0.0003, R2=1.0000

2nd lot of reagent: Y=0.9993X - 0.0023, R2=0.9999
3rd lot of reagent: Y=0.9994X - 0.0229, R2=1.0000

IFCC unit:

1st lot of reagent: Y=0.9977X - 0.0854, R2=1.0000
2nd lot of reagent: Y=0.9992X - 0.0235, R2=0.9999
3rd lot of reagent: Y=0.9996X - 0.2595, R2=1.0000

Hemolysate

NGSP unit:

1st lot of reagent: Y=0.9973X - 0.0183, R2=0.9999
2nd lot of reagent: Y=1.0014X - 0.0296, R2=1.0000
3rd lot of reagent: Y=0.9999X - 0.0244, R2=1.0000

IFCC unit:

1st lot of reagent: Y=0.9974X - 0.2502, R2=0.9999
2nd lot of reagent: Y=1.0017X - 0.2954, R2=1.0000
3rd lot of reagent: Y=1.0000X - 0.2639, R2=1.0000

Results of the linearity study support the claimed measuring range of the device of 3.0% to 20.0% HbA1c (9.3-195.1 mmol/mol).

3. Analytical Specificity/Interference:

Interference studies were performed to assess the impact of endogenous and exogenous substances on the performance of the H100Plus Hemoglobin Testing 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 Tested with No Significant Interference (mg/dL)
Unconjugated Bilirubin	100
Conjugated Bilirubin	100
Glucose	2,000
Rheumatoid Factors	750 IU/mL
Lipemia	6,000
Total Protein	21,000
Triglycerides	2,000
Albumin (human)	20,000

Exogenous Substances

Interferent	Highest Concentration Tested with No Significant Interference (mg/dL)
Acetylcysteine	330

Interferent	Highest Concentration Tested with No Significant Interference (mg/dL)
Ampicillin-Na	1,000
Ascorbic acid	300
Cefoxitin	2,500
Heparin	5,000 U/L
Levodopa	20
Methyldopa	30
Metronidazole	200
Doxycyclin	50
Rifampicin	64
Cyclosporine	5
Acetaminophen	200
Ibuprofen	500
Theophylline	100
Phenylbutazone	400
Salicylic acid	60

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 incubated at 37℃ for 3 hours to prepare hemoglobin derivatives. 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.
- Labile A1c - (up to 60 mg/dL Acetaldehyde) 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 500 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 Lifotronic Hemoglobin Test System (HPLC) and the results compared to those obtained using comparator methods that have been demonstrated to be free from interference by these hemoglobin variants. The sponsor defined significant interference as ≥6% 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

Hemoglobin Variant	Number of Samples	Variant Concentration Range (%)	Range of HbA1c Concentration (%)
HbS	25	38 – 42	5.8 – 10.4
HbC	25	30 – 38	5.7 – 10.0
HbD	25	40 – 42	5.7 – 11.7
HbE	27	23 – 32	5.8 – 11.8
HbA2	25	3.5– 6.7	5.0 – 9.0
HbF	25	3.0 – 30	5.5 – 10.4

Summary of Hemoglobin Variant Test Results

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	0.69	-1.61 to 0.81	0.63	-0.87 to 1.93
HbC	0.65	-1.25 to 0.88	0.60	-0.80 to 1.73
HbD	0.81	-1.88 to 0.92	0.84	-1.37 to -1.54
HbE	0.78	-1.72 to 0.98	0.68	-0.85 to 1.87
HbA2	0.78	-1.89 to 0.93	0.69	-1.52 to 1.08
HbF	0.55	-1.61 to 0.76	0.81	-1.46 to 0.98

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

4. Detection Limit and Assay Reportable Range:
   The reportable range for this device is 3.0% – 20.0% HbA1c (NGSP) or 9.3 – 195.1 mmol/mol HbA1c (IFCC).

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

   The H100Plus Hemoglobin Testing 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 https://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 × IFCC (mmol/mol) + 2.152.

6. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison study was performed using 129 variant-free K2-EDTA venous whole blood samples (3.0 to 20.0% HbA1c concentration range) comparing the candidate device results with those from the predicate device (i.e., Bio-Rad D-100 HbA1c Test) performed at a NGSP secondary reference laboratory. The study was conducted using both the whole blood and hemolysate modes of the H100Plus Hemoglobin Testing System. The distribution of samples spanning the measuring interval is as follows:

HbA1c levels, %	# of samples tested	% of sample tested
≤ 5	6	4.7
5.0 – 6.0	17	13.2
6.0 – 6.5	31	24.0
6.5 – 7.0	33	25.6
7.0 – 8.0	20	15.5
8.0 – 9.0	11	8.5
> 9.0	11	8.5
Total	129	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	1.0060	1.0002 to 1.0117	-0.0237	-0.0721 to 0.0247
Passing-Bablok	0.9974	0.9815 to 1.0068	0.0513	-0.0248 to 0.1515

Hemolysate mode, NGSP unit:

Method	**Slope**	**95% CI**	**y-intercept**	**95% CI**
Deming	1.0070	0.9983 to 1.0156	-0.0197	-0.0839 to 0.0449
Passing-Bablok	0.9958	0.9800 to 1.0071	0.0649	-0.0186 to 0.1740

Bias Estimation for the whole blood mode:

HbA1c levels (%)	**Deming**		**Passing-Bablok**	
	Bias (%)	**%Bias**	**Bias (%)**	**%Bias**
5.0	0.0063	0.1260	0.0383	0.7660
6.5	0.0153	0.2354	0.0344	0.5292
8.0	0.0243	0.3038	0.0305	0.3813
12.0	0.0483	0.4025	0.0201	0.1675

Bias Estimation for the hemolysate mode:

HbA1c levels (%)	Deming		Passing-Bablok	
	Bias (%)	%Bias	Bias (%)	%Bias
5.0	0.0153	0.3060	0.0439	0.8780
6.5	0.0258	0.3969	0.0376	0.5785
8.0	0.0363	0.4538	0.0313	0.3912
12.0	0.0643	0.5358	0.0145	0.1208

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

Total Error for the whole blood mode:

Regression	HbA1c levels, %	%Bias	%CV	%TE
Deming	5.0	0.1260	1.18	2.44
	6.5	0.2354	1.13	2.46
	8.0	0.3038	1.06	2.39
	12.0	0.4025	0.98	2.33
Passing-Bablok	5.0	0.7660	1.18	3.10
	6.5	0.5292	1.13	2.76
	8.0	0.3813	1.06	2.47
	12.0	0.1675	0.98	2.09

Total Error for the hemolysate mode:

Regression	HbA1c levels, %	%Bias	%CV	%TE
Deming	5.0	0.3060	1.21	2.68
	6.5	0.3969	1.15	2.66
	8.0	0.4538	1.05	2.52
	12.0	0.5358	0.95	2.41
Passing-Bablok	5.0	0.8780	1.21	3.27
	6.5	0.5785	1.15	2.85
	8.0	0.3912	1.05	2.46
	12.0	0.1208	0.95	1.99

2. Matrix Comparison:

The effect of anticoagulants on Hemoglobin A1c determination by the H100Plus Hemoglobin Testing System was determined by comparing HbA1c results obtained from venous K2-EDTA and venous K3-EDTA samples. 50 paired samples in each anticoagulant with %HbA1c concentrations ranging from 3.1% to 20.0% were collected from 50 donors and evaluated once on the device. The following are results from ordinary least squares regression analysis:

Sample	Unit	Slope	Intercept	R^2
	NGSP, %	0.9995	0.0244	0.9997

Whole blood	IFCC (mmol/mol)	0.9995	0.2576	0.9997

The results support the use of the HbA1c assay with samples collected in K2-EDTA and K3-EDTA.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Clinical Cut-Off

   Not applicable.

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

   Not applicable.

D Expected Values/Reference Range:

The sponsor provided the following expected values in their labeling:

Hemoglobin A1c		Suggested Diagnosis
NGSP %	IFCC mmol/mol	
≥6.5	≥48	Diabetic[1-3]
5.7–6.4	39–47	Pre-Diabetic[2]
<5.7	<39	Non-Diabetic

[1]World Health Organization. Use of glycated Haemoglobin (HbA1c) in the diagnosis of diabetes mellitus: abbreviated report of a WHO consultation. Geneva, 2011:1-25.
[2]American Diabetes Association Professional Practice Committee. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes—2026. Diabetes Care. 2026;49 (Suppl 1):S27-S49.
[3]International Expert Committee. Report on the Role of the A1c Assay in the Diagnosis of Diabetes. Diabetes Care 2009, 32 (7), 1327-1334.

E Other Supportive Instrument Performance Characteristics Data:

- EMC and Electrical Safety

The sponsor provided documentation certifying that acceptable electrical safety and (EMC) testing had been performed and the H100Plus Hemoglobin Testing System was found to be compliant.

- Software and Cybersecurity
  The sponsor provided software and cybersecurity documentation that was reviewed and found to be acceptable.

- Additional studies were performed and found to be acceptable to support claims of 10,000 run of the HPLC column, the operation conditions of the system, and no carryover from sample to sample.

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.