July 12, 2018

Sekisui Diagnostics PEI Inc.
Penny White
Regulatory Affairs Manager
70 Watts Ave.
Charlottetown, Prince Edward Island
C1E 2B9 Canada

Re: K173206
Trade/Device Name: SEKURE HbA1c Assay
Regulation Number: 21 CFR 862.1373
Regulation Name: Hemoglobin A1c Test System
Regulatory Class: Class II
Product Code: PDJ, LCP
Dated: May 31, 2018
Received: June 4, 2018

Dear Penny White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173206

Device Name
SEKURE HbA1c Assay

Indications for Use *(Describe)*
The SEKURE HbA1c assay is used to measure the percent concentration of hemoglobin A1c (NGSP) or the HbA1c fraction mmol/mol (IFCC) in human venous whole blood and hemolysate on the SK500 Clinical Chemistry System. Measurement of HbA1c is used as an aid in the diagnosis of diabetes mellitus, as an aid in the identification of patients at risk for development of diabetes mellitus, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus.
For In Vitro Diagnostic Use Only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 510k Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR §807.92. This is a Traditional 510(k).

The assigned 510(k) number: K173206

5.1. Applicant Information and Date [807.92(a) (1)]

Applicant Name and Address:	SEKISUI DIAGNOSTICS P.E.I. INC. 70 Watts Avenue, Charlottetown, PE Canada, C1E 2B9 Establishment Registration Number: 8020316
Application correspondent:	Penny White Regulatory Affairs Manager 902-628-0934 Penny.white@sekisuidiagnostics.com
Date Summary prepared:	06 July 2018

5.2. Device Name and Classification [807.92 (a)(2)]

Trade Name	Common Name	Classification Name	Regulation	Classification	Product Code	Panel
SEKURE HbA1c Assay	Hemoglobin A1c Test System	Hemoglobin A1c Test System	21 CFR 862.1373	Class II	PDJ	Clinical Chemistry
			21 CFR 864.7470	Class II	LCP	Hematology

5.3. Identification of Legally Marketed Predicate Devices [807.92(a)(3)]

Trade Name	Predicate Device	Predicate 510(k) Number
SEKURE HbA1c Assay	Architect Hemoglobin A1c	K130255

5.4. Device Description [807.92 (a)(4)]

Trade Name	Device Description
SEKURE HbA1c Assay	The SEKURE HbA1c assay is an enzymatic assay for the measurement of the percent hemoglobin A1c concentration. The assay consists of a pre-treatment hemolyzing buffer solution and two working reagents. Testing is performed on the SK500 K103531in conjunction with calibrators and controls which will be provided separately.
NGSP Manufacturer Certification	Sekisui has obtained NGSP manufacturer certification for the SEKURE HbA1c assay on the SK500. The certification process included a method comparison of 40 patient samples with a Secondary Reference Laboratory and an assessment of the agreement analysis.
SK500 Clinical Chemistry Analyzer	The SK500 Analyzer is manufactured as Clinical Chemistry Analyzer Tokyo Boeki Medisys Inc. Biolis 50i Superior, cleared under K103531. "SK500" is the Sekisui Diagnostics labeled name for the Tokyo Boeki Medisys Inc. Biolis 50i Superior instrument.

5.5. Intended Use [807.92 (a)(5)]

Trade Name	Intended Use
SEKURE HbA1c Assay	The SEKURE HbA1c assay is used to measure the percent concentration of hemoglobin A1c (NGSP) or the HbA1c fraction mmol/mol (IFCC) in human venous whole blood and hemolysate on the SK500 Clinical Chemistry System. Measurement of HbA1c is used as an aid in the diagnosis of diabetes mellitus, as an aid in the identification of patients at risk for development of diabetes mellitus, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus. For In Vitro Diagnostic Use Only

5.6. Technological Similarities and Differences to the Predicate [807.92 (a)(6)]

The SEKURE HbA1c Assay included in the submission each have a predicate device, as described in the tables below.

5.6.1 SEKURE HbA1c Assay

Characteristic	Predicate Device	New Device
	Hemoglobin A1c Abbott Laboratories	**SEKURE HbA1c Assay**
Intended Use	The HbA1c assay is used in clinical laboratories for the quantitative in vitro measurement of hemoglobin A1c or HbA1c fraction mmol/mol (IFCC) in human whole blood and hemolysate on the ARCHITECT c 8000 System. HbA1c measurement is used as an aid in the diagnosis of diabetes mellitus and as and 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.	The SEKURE HbA1c assay is used to measure the percent concentration of HbA1c (NGSP) or the HbA1c fraction mmol/mol (IFCC) in human venous whole blood and hemolysate on the SK500 Clinical Chemistry System. Measurement of hemoglobin A1c is used as an aid in the diagnosis of diabetes mellitus, as an aid in the identification of patients who may be at risk for development of diabetes mellitus, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus. For In Vitro Diagnostic Use Only.

Characteristic	Predicate Device	New Device
	Hemoglobin A1c Abbott Laboratories	**SEKURE HbA1c Assay**
Platform	ARCHITECT c 8000 (Clinical Chemistry Analyzer)	SK500 (K103531) (Clinical Chemistry Analyzer)
Methodology	Enzymatic	SAME
Specimen type	Whole blood and hemolysate Dipotassium EDTA Lithium Heparin Sodium Heparin Sodium fluoride/disodium EDTA Tripotassium EDTA	Whole blood and Hemolysate Dipotassium EDTA Sodium fluoride/disodium EDTA Tripotassium EDTA
Measuring interval	4.0 to 14.0% HbA1c (DCCT/NGSP) 20.22-129.51 mmol/mol HbA1c (IFCC)	4.0 to 14.0% HbA1c (DCCT/NGSP) 20.02 to 129.34 mmol/mol HbA1c

5.7. Summary of Non-Clinical Performance Data [807.92 (b)(1)]

5.7.1 SEKURE HbA1c Assay

Precision

Testing was conducted using 3 lots of HbA1c Reagents and Calibrators and 3 instruments. Two levels of controls and 4 levels of human whole blood pools were assayed in 2 replicates at 2 separate times per day for 20 different days. Each reagent lot was calibrated fresh daily.

IFCC
The HbA1c assay is designed to have an imprecision of ≤4.5% within laboratory %CV.

NGSP
The HbA1c assay is designed to have an imprecision of ≤2.5% within laboratory %CV.

Precision, All Instruments, Whole Blood, NGSP Units (%HbA1c)

		Repeatability		Between Run		Between Day		Between Instruments		Between Lot		Total Precision	
Sample	Mean	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
QC 1	5.23	0.055	1.1	0.028	0.5	0.056	1.1	0.053	1.0	0.009	0.2	0.083	1.6
QC 2	9.77	0.064	0.7	0.037	0.4	0.061	0.6	0.041	0.4	0.004	0.0	0.096	1.0
Patient 1	5.01	0.044	0.9	0.034	0.7	0.041	0.8	0.056	1.1	0.007	0.1	0.069	1.4
Patient 2	6.33	0.045	0.7	0.037	0.6	0.047	0.7	0.059	0.9	0.011	0.2	0.074	1.2
Patient 3	7.79	0.037	0.5	0.044	0.6	0.045	0.6	0.059	0.8	0.015	0.2	0.074	0.9
Patient 4	12.07	0.036	0.3	0.049	0.4	0.067	0.6	0.061	0.5	0.021	0.2	0.091	0.8

Precision, All Instruments, Hemolysate, NGSP Units (%HbA1c)

		Repeatability		Between Run		Between Day		Between Instruments		Between Lot		Total Precision	
Sample	Mean	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
QC 1	4.99	0.048	1.0	0.032	0.6	0.035	0.7	0.015	0.3	0.009	0.2	0.067	1.4
QC 2	9.61	0.037	0.4	0.046	0.5	0.036	0.4	0.021	0.2	0.009	0.1	0.069	0.7
Patient 1	5.00	0.033	0.7	0.032	0.6	0.037	0.7	0.059	1.2	0.008	0.2	0.060	1.2
Patient 2	6.34	0.036	0.6	0.036	0.6	0.041	0.6	0.057	0.9	0.011	0.2	0.066	1.0
Patient 3	7.81	0.029	0.4	0.055	0.7	0.037	0.5	0.057	0.7	0.017	0.2	0.073	0.9
Patient 4	12.05	0.048	0.4	0.47	0.4	0.054	0.5	0.058	0.5	0.021	0.2	0.086	0.7

Precision, All Instruments, Whole Blood, IFCC Units (mmol/mol)

		Repeatability		Between Run		Between Day		Between Instruments		Between Lot		Total Precision	
Sample	Mean	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
QC 1	33.60	0.600	1.8	0.302	0.9	0.617	1.8	0.576	1.7	0.101	0.3	0.912	2.7
QC 2	83.33	0.698	0.8	0.407	0.5	0.667	0.8	0.451	0.5	0.048	0.1	1.047	1.3
Patient 1	31.19)	0.482	1.5	0.74	1.2	0.452	1.4	0.612	2.0	0.081	0.3	0.759	2.4
Patient 2	45.64	0.488	1.1	0.406	0.9	0.509	1.1	0.643	1.4	0.118	0.3	0.814	1.8
Patient 3	61.66	0.406	0.7	0.486	0.8	0.495	0.8	0.650	1.1	0.166	0.3	0.804	1.3
Patient 4	108.43	0.394	0.4	0.539	0.5	0.731	0.7	0.669	0.6	0.227	0.2	0.990	0.9

Precision, All Instruments, Hemolysate, IFCC Units (mmol/mol)

		Repeatability		Between Run		Between Day		Between Instruments		Between Lot		Total Precision	
Sample	Mean	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
QC 1	31.02	0.524	1.7	0.351	1.1	0.380	1.2	0.166	0.5	0.104	0.3	0.736	2.4
QC 2	81.57	0.402	0.5	0.500	0.6	0.395	0.5	0.226	0.3	0.100	0.1	0.754	0.9
Patient 1	31.13	0.366	1.2	0.354	1.1	0.409	1.3	0.650	2.1	0.092	0.3	0.653	2.1
Patient 2	45.74	0.398	0.9	0.397	0.9	0.449	1.0	0.629	1.4	0.117	0.3	0.719	1.6
Patient 3	61.80	0.314	0.5	0.604	1.0	0.408	0.7	0.624	1.0	0.182	0.3	0.794	1.3
Patient 4	108.20	0.528	0.5	0.510	0.5	0.593	0.5	0.632	0.6	0.234	0.2	0.944	0.9

Analytical Sensitivity

Limit of Blank (LoB) and Limit of Detection (LoD):
Limit of Blank and Limit of Detection testing was based on guidance from the CLSI guidance document EP17-A2. Testing was completed by analyzing 5 blank samples and 5 low concentration samples in quadruplicate for 3 days producing a total of 60 measurements of each level using 2 lots of SEKURE HbA1c reagent on two SK500 analyzers. Low concentration samples were dilutions of dipotassium EDTA venous whole blood.

Limit	%HbA1c	µmol/L A1c	µmol/L THb
Limit of Blank (LoB)	3.27	0.66	0.2
Limit of Detection (LoD)	3.32	0.75	0.5

Linearity/Assay Reportable Range:
A linearity study was performed based on guidance from the CLSI guidance document EP06-A. The linearity study was performed using two lots of SEKURE HbA1c reagent on one SK500. A dilution series consisting of 11 levels across the assay range were prepared by mixing high and low HbA1c dipotassium EDTA venous whole blood samples. Samples were run in quadruplicate, mean values are presented.

IFCC
The HbA1c assay is linear across the range of 20.02 to 129.34 mmol/mol HbA1c based on an allowable tolerance of within or equal to ±7%.

NGSP
The HbA1c assay is linear across the range of 4.0 to 14.0 %HbA1c based on an allowable tolerance of within or equal to ±7%.

The linearity study supports an assay measuring range of 4.0 to 14.0% HbA1c (20.02 to 129.34 mmol/mol IFCC).

Traceability, Stability, Expected Values (controls calibrators or methods):

Traceability:
The SEKURE HbA1c Assay standardization is traceable to the International Federation of Clinical Chemistry (IFCC) reference calibrators. The SEKURE HbA1c Assay is NGSP certified. The NGSP certification expires in one year. The derived result of (%) from the NGSP correlation is calculated from the individual quantitative results for the total hemoglobin and hemoglobin A1c (HbA1c). The IFCC units of mmol/mol are calculated using the equation IFCC = (NGSP-2.152) / 0.09148. Two different units are provided to users: NGSP equivalent units (%) and IFCC equivalent units (mmol/mol).

Value Assignment:
The SEKURE HbA1c calibrators are aligned to IFCC reference calibrators through internal value assignment in which the calibrator values must meet the pre-determined acceptance criteria within a set specification. Each lot of calibrators is value-assigned. The concentration of glycated hemoglobin (HbA1c) and total hemoglobin (THb) is provided for each lot. Calibrators are prepared gravimetrically, lyophilized and then value assigned using secondary calibrators that are traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) reference method.

The value assigned HbA1c concentration falls within the following HbA1c ranges:

Calibrator 1: 4.59% to 6.02% HbA1c

Calibrator 2: 10.52% to 13.37% HbA1c

The SEKURE HbA1c Controls are value assigned using the secondary calibrators. The values obtained must meet the pre-determined acceptance criteria.

The value-assigned HbA1c Control values are within the following HbA1c ranges:

Control L: 4.59% to 6.02% HbA1c

Control H: 9.42% to 11.07 % HbA1c

Stability:

Shelf-life claims: Current testing supports a shelf life of 11 months for un-opened calibrators and controls stored at 2-8 °C. Testing is ongoing to extend the shelf life further.

Onboard Stability for the SK500 was established by real time studies on the SK500 analyzer and demonstrated on-board reagent stability of 28 days. Current testing supports a stability of 11 months for un-opened SEKURE HbA1c Assay. Testing is ongoing to extend the shelf life further.

Analytical Specificity (Endogenous and Exogenous Interference)

An interference study was performed based on the CLSI EP7-A2 guideline to assess common or known substances that could interfere with the HbA1c Assay. Interference testing was conducted using 2 lots of SEKURE HbA1c reagent. All interferents were tested at % HbA1c concentrations of ~ 6.5 and 8.0% in replicates of ten. Significant interference was identified as a percent difference greater than 5% from control.

The interference study results are summarized in the following table:

Potential Interferent	Highest Tested Concentration at which no significant interference (>5%) was observed	
	Conventional Units	SI Units
Conjugated Bilirubin	18 mg/dL	216 µmol/L
Unconjugated Bilirubin	18 mg/dL	307.8 µmol/L
Total Protein	22 g/dL	220 g/L
Triglycerides	3000 mg/dL	33.9 mmol/L
Rheumatoid Factor	200 IU/mL	200 IU/mL
Ascorbic Acid	3.0 mg/dL	0.15 mmol/L
Glucose	1000 mg/dL	55.5 mmol/L
Urea	667 mg/dL	111.06 mmol/L
Vitamin E	8.6 mg/dL	200 µmol/L

The HbA1c assay is susceptible to interference effects from conjugated bilirubin at > 18 mg/dL (216 µmol/L) and unconjugated bilirubin at > 18 mg/dL (307.8 µmol/L). The bias at 18 mg/dL conjugated bilirubin is -4.2% and the bias at 18 mg/dL unconjugated bilirubin is -4.5%.

Potential drug interference testing was performed based on the CLSI EP7-A2 guideline to assess common or known drugs that could interfere with the HbA1c Assay. All potential drug interferents were tested at % HbA1c concentrations of ~ 6.5 and 8.0% in replicates of ten. Significant interference was identified as a percent difference greater than 5% from control.

The drug interference study results are summarized in the following table:

Potential Drug Interferent	Highest Tested Concentration at which no significant interference (>5%) was observed	
	Conventional Units	SI Units
Acarbose	50 mg/dL	0.77 mmol/L
Acetaminophen	20 mg/dL	1324 µmol/L
Acetylsalicylate	50.8 mg/dL	2.82 mmol/L
Atorvastatin	0.06mg/dL	600 µg Eq/L
Captopril	0.5 mg/dL	23 µmol/L
Chlorpropamide	74.7 mg/dL	2.7 mmol/L
Cyanate	65 mg/dL	10 mmol/L
Furosemide	6.0 mg/dL	181 µmol/L
Gemfibrozil	7.5 mg/dL	300 µmol/L
Ibuprofen	50 mg/dL	2425 µmol/L
Insulin	450 µU/mL	450 µU/mL
Losartan	5 mg/dL	0.11 mmol/L
Metformin	5.1 mg/dL	310 µmol/L
Nicotinic Acid	61 mg/dL	4.95 mmol/L
Propranolol	0.2 mg/dL	7.71 µmol/L
Repaglinide	0.006 mg/dL	132.57 nmol/L

Hemoglobin Variants

The hemoglobin variant study was performed according to guidance from the CLSI EP7-A2. The interference effects of the hemoglobin variants were assessed by comparing the HbA1c values to a comparative method for samples containing potentially interfering hemoglobin variants. The number and concentrations hemoglobin variants tested, and the range of % HbA1c concentrations in which they were tested are shown below:

Hemoglobin Variant	**n**	**Range in % Abnormal Variant**	**Range in % HbA1c Concentration**
HbA2	36	4.1 – 6.2	4.06 – 10.0
HbC	14	27.4 – 38.4	4.81 – 10.46
HbD	25	19.6 – 40.0	4.79 – 12.62
HbE	22	24.0 – 28.0	5.2 – 10.0
HbF	25	4.4 – 29.3	5.1 – 12.8
HbS	15	28.2 – 37.5	4.45 – 12.31

The results for the hemoglobin variant study are summarized below:

Hemoglobin Variant	Relative % Difference from Reference Concentration at Low and High Concentrations			
	~ 6.0 % HbA1c (5.5 to 6.5 %HbA1c)		~ 9.0 %HbA1c (7.5 to 10.5 %HbA1c)*	
	Relative % Difference	Range	Relative % Difference	Range
HbA2	-2.28	-5.56 to 5.08	-1.28	-2.30 to -0.14
HbC	-1.64	-3.30 to 1.90	-0.97	-1.72 to -0.38
HbD	0.10	-5.69 to 2.91	-1.14	-2.83 to 0.67
HbE	3.41	1.85 to 5.42	3.50	-0.50 to 6.34
HbF	-15.42	-23.06 to -6.25	-15.33	-21.73 to -4.81
	HbF interferes with this assay			
HbS	1.83	0.51 to 2.40	0.41	-0.94 to 1.73

*The HbA2 results at ~9.0 %HbA1c consisted of samples between 7.2 – 10.0% HbA1c

There was no significant (Relative % Difference >5%) interference observed for HbA2, HbC, HbD, HbE or HbS at the concentrations tested above. There was significant negative interference with fetal hemoglobin (HbF). HbA1c results are not valid for patients with elevated levels of HbF, including those with known Hereditary Persistence of Fetal Hemoglobin. A warning to this effect will be included in product labeling.

5.8 Summary of Method Comparison

Method comparison with Predicate Device:

Method comparison testing was conducted based on CLSI EP09-A3 on 2 SK500 analyzers using 2 lots of SEKURE HbA1c reagent. Testing was completed on 130 dipotassium EDTA whole blood specimens over 5 operating days in duplicate. Samples were assayed using both online (whole blood) and offline hemolysis (hemolysate) using the SEKURE HbA1c assay on the SK500.

The sample range tested was 4.3 to 13.8% NGSP. The distribution of samples spanned the measuring interval with a concentration of samples around the clinical decision points as demonstrated in the table below.

Method Comparison Sample Range Summary

Hemoglobin A1c level	n	% Samples tested
≤ 5%	6	4.6
5 – 6%	11	8.5
6 – 6.5%	34	26.2
6.5 – 7%	33	25.4
> 7%	46	35.3
Total samples	130	100

First replicate analysis is summarized below. The Hemoglobin A1c assay is designed to have a slope of 1.1 ± 0.10 and a correlation coefficient (r) of ≥ 0.95 for specimens across the measuring interval when compared to an NGSP secondary reference laboratory method.

A correlation study was performed using CLSI protocol EP09-A3 with Passing-Bablok regression and Deming analysis. Human venous whole blood specimen results from the SEKURE Hemoglobin A1c assay were compared with those from an NGSP secondary reference laboratory method.

The data are summarized in the following tables:

Whole blood: Passing-Bablok Regression

Units	Comparison Assay (x)	N	r	Regression Equation	Sample Range
NGSP	NGSP Reference Method	130	0.9977	y = 0.974x + 0.007	4.30 to 13.80
IFCC	NGSP Reference Method	130	0.9977	y = 0.974x – 0.671	23.48 to 127.33

Hemolysate: Passing-Bablok Regression

Units	Comparison Assay (x)	N	r	Regression Equation	Sample Range
NGSP	NGSP Reference Method	130	0.9981	y = 0.969x + 0.101	4.30 to 13.80
IFCC	NGSP Reference Method	130	0.9981	y = 0.969 + 0.185	23.48 to 127.33

Whole blood: Deming Regression

Units	Comparison Assay (x)	N	r	Regression Equation	Sample Range
NGSP	NGSP Reference Method	130	0.9977	y = 0.987x – 0.087	4.30 to 13.80
IFCC	NGSP Reference Method	130	0.9977	y = 0.987x – 1.442	23.48 to 127.33

Hemolysate: Deming Regression

Units	Comparison Assay (x)	N	r	Regression Equation	Sample Range
NGSP	NGSP Reference Method	130	0.9981	y = 0.984x – 0.012	4.30 to 13.80
IFCC	NGSP Reference Method	130	0.9981	y = 0.984x - 0.706	23.48 to 127.33

Bias (NGSP)
The HbA1c assay is designed to have a bias of ≤ 3% at 5.0, 6.5, 8.0 and 12.0 %HbA1c using Passing- Bablok regression.

The bias in %HbA1c (NGSP) ranged from -2.40 to -2.50%.

Total Error Near the Cutoff
Using the results of bias estimation (%Bias) in the method comparison study and precision estimates in the reproducibility study, the Total Error (TE) at the following concentrations (5%, 6.5%, 8% and 12%) was calculated as follows: %TE =|%Bias| + 1.96 * %CV * (1+%Bias/100). The results are presented in the tables below.

% Total Error Summary – Whole Blood (NGSP) Passing Bablok

% A1c – Decision Level	% Bias	% CV	% TE
5.0	-2.40	1.4	5.08
6.5	-2.46	1.2	4.75
8.0	-2.50	0.9	4.22
12.0	-2.50	0.8	4.03

% Total Error Summary – Hemolysate (NGSP) Passing Bablok

% A1c – Decision Level	% Bias	% CV	% TE
5.0	-1.20	1.2	3.52
6.5	-1.54	1.0	3.47
8.0	-1.88	0.9	3.61
12.0	-2.33	0.7	3.67

% Total Error Summary – Whole Blood (NGSP) Deming

% A1c – Decision Level	% Bias	% CV	% TE
5.0	-3.04	1.4	5.70
6.5	-2.64	1.2	4.93
8.0	-2.39	0.9	4.11
12.0	-2.03	0.8	3.56

% Total Error Summary – Hemolysate (NGSP) Deming

% A1c – Decision Level	% Bias	% CV	% TE
5.0	-1.84	1.2	4.15
6.5	-1.78	1.0	3.71
8.0	-1.75	0.9	3.48
12.0	-1.70	0.7	3.05

Matrix Comparison:
A matrix study was performed to determine the suitability of various anticoagulants for use with the SEKURE HbA1c Assay. The evaluation of different anticoagulants was completed using two lots of reagents, and 41 matched patient specimens analyzed in duplicate. Sample %HbA1c concentrations s panned the range of the assay.

The first replicate Passing-Bablok regression analysis data is summarized in the following table:

Control Tube – Dipotassium EDTA

Specification	Acceptance Criteria	Tripotassium EDTA		Sodium Fluoride/Disodium EDTA	
		Lot 1	Lot 2	Lot 1	Lot 2
%Bias	5%	0.72	0.80	-0.51	-0.42
Slope	1.0 ± 0.1	1.015	0.998	1.006	0.995
Intercept	N/A	-0.043	0.062	-0.084	-0.021
Correlation Coefficient	≥ 0.95	0.9992	0.9992	0.9994	0.9994
Pass/Fail		Pass	Pass	Pass	Pass

The data supports the use of the following blood collection tubes with the SEKURE HbA1c assay:

- Dipotassium EDTA (control tube)
- Sodium Fluoride/Disodium EDTA
- Tripotassium EDTA

Clinical studies:
(*clinical sensitivity, clinical specificity, other clinical supportive data)*
Not Applicable

Expected values/Reference Range:
HbA1c values above 6.5 %HbA1c (48 mmol/mol) meet the criteria for diagnosis of diabetes mellitus.[1] Patients with HbA1c values in the range of 5.7 - 6.4 %HbA1c (39 - 47 mmol/mol) are at an increased risk for diabetes (pre-diabetes).[1] HbA1c levels below 5.7 %HbA1c (39 mmol/mol) are considered normal.[1]

1. American Diabetes Association Position Statement: Standards of medical care in diabetes – 2018. In: Diabetes Care 2018; 41 (Suppl 1): S13-S64.

Verification of the Reference Range was conducted using two lots of SEKURE HbA1c reagent and fresh blood from 20 clinically healthy patient samples tested in singlicate.

The data in %HbA1c are summarized in the following table:

	SEKURE HbA1c Lot 1	SEKURE HbA1c Lot 2
Reference Range*	4.8 – 5.9%	4.8 to 5.9%
Observed Range	4.60 to 5.66	4.74 to 5.83
Verification Range x – 1/3(y-x) to y +1/3(y-x) where x = smallest value y = largest value	4.43 to 6.27	4.43 to 6.27
Samples within verification range	20/20	20/20
Pass/Fail	Pass	Pass

*Source: ROCHE – Reference Ranges for Adults, Pre-Analytical Considerations - 2008

5.8 Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

5.9. Conclusion

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