September 12, 2024

Shijiazhuang Hipro Biotechnology Co., Ltd.
% Hanson Chen, Official Correspondent
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A
Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District
Shenzhen, Gaungdong 518000
China

Re: K220999
Trade/Device Name: Hipro Glycosylated Hemoglobin (HbA1c) Test System
Regulation Number: 21 CFR 862.1373
Regulation Name: Hemoglobin A1c Test System
Regulatory Class: Class II
Product Code: PDJ, LCP
Dated: October 13, 2023
Received: October 13, 2023

Dear Hanson Chen:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
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OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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)*
K220999

Device Name
Hipro® Glycosylated Hemoglobin (HbA1c) Test System

Indications for Use *(Describe)*
The Hipro® Glycosylated Hemoglobin (HbA1c) Test System comprised of the Hipro Glycosylated hemoglobin (HbA1c) test kit and the HP-AFS/1 automatic immunoassay analyzer is used as an aid in diagnosis of diabetes mellitus, 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. It is an in vitro diagnostics reagent system intended for quantitative determination of % hemoglobin A1c (DCCT/NGSP) in venous whole blood.

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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510(k) Summary k220999

1. Contact Details

1.1 Applicant information

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Date Prepared	Sep 12, 2024
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1.2 Submission Correspondent

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Contact person's e-mail	hanson@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Hipro® Glycosylated Hemoglobin (HbA1c) Test System
Model	/
Classification	Ⅱ
Classification name	Hemoglobin A1c Test System
Product code	PDJ, LCP
Regulation No.	862.1373

3. Legally Marketed Predicate Device

Trade Name	D-100™ HbA1c
510(k) Number	K151321
Product Code	PDJ, LCP
Manufacturer	Bio-Rad Laboratories, Inc.

4. Device Description

The Hipro® Glycosylated hemoglobin (HbA1c) test system is intended for quantitative determination of % hemoglobin A1c (DCCT/NGSP) in venous whole blood. It is composed of Glycosylated hemoglobin (HbA1c) test kit and automatic immunoassay analyzer. Glycosylated hemoglobin (HbA1c) test kit consists of two reagents R1 and R2, which are liquid and ready to use. Reagent R1 contains glycine buffer and latex, and reagent R2 contains glycine buffer and two types of antibodies, Goat anti-mouse IgG, mouse anti-human HbAlc monoclonal antibody.

HP-AFS/1 Automatic Immunoassay Analyzer is made up of light absorption test module, scattered light test module, fluorescence test module, press components, data transmission interface and printer. And the absorption test module is made up of absorption light path unit, and light-absorption sensor part. The scattered light test module is made up of scattered light path unit and scattered light sensor part.

5. Intended Use/Indication for Use

The Hipro® Glycosylated Hemoglobin (HbA1c) Test System comprised of the Hipro Glycosylated hemoglobin (HbA1c) test kit and the HP-AFS/1 automatic immunoassay analyzer is used as an aid in diagnosis of diabetes mellitus, 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. It is an in vitro diagnostics reagent system intended for quantitative determination of % hemoglobin A1c (DCCT/NGSP) in venous whole blood.

6. Substantial Equivalence Comparison

Item	Candidate Device: Hipro® Glycosylated Hemoglobin (HbA1c) Test System	Predicate Device: D-100™ HbA1c (K151321)
Regulation number	862.1373	862.1373
Classification	Ⅱ	Ⅱ
Product Code	PDJ, LCP	PDJ, LCP

Item	Candidate Device: Hipro® Glycosylated Hemoglobin (HbA1c) Test System	Predicate Device: D-100™ HbA1c (K151321)
Intended use/Indications for use	The Hipro® Glycosylated Hemoglobin (HbA1c) Test System comprised of the Hipro Glycosylated hemoglobin (HbA1c) test kit and the HP-AFS/1 automatic immunoassay analyzer is used as an aid in diagnosis of diabetes mellitus, 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. It is an in vitro diagnostics reagent system intended for quantitative determination of % hemoglobin A1c (DCCT/NGSP) in venous whole blood.	The D-100™ HbA1c test is intended for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human whole blood using ion-exchange high-performance liquid chromatography (HPLC) on the D-100 Hemoglobin Testing System. Hemoglobin A1c measurements are used as an aid in diagnosis of diabetes mellitus, 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. The D-100™ HbA1c test is intended for Professional Use Only.
Methodology	Nephelometry Immunoassay Method	Ion-exchange HPLC
Testing Environment	Prescription use	Prescription use
Specimen type	Human Whole blood	Human Whole blood
Matrices	K2-EDTA	K2-EDTA K3-EDTA Potassium Oxalate/Sodium Fluoride, Sodium Citrate, Sodium Heparin, Lithium Heparin
Reporting Units	% HbA1c NGSP/DCCT	% HbA1c NGSP/DCCT and mmol/mol IFCC
Measurement range	4.3-14% HbA1c	3.5-20 % HbA1c 15-195 mmol/mol HbA1c

Item	Candidate Device: Hipro® Glycosylated Hemoglobin (HbA1c) Test System	Predicate Device: D-100™ HbA1c (K151321)
Reagent Stability	2-8ºC for 12 months	On-board stability for the D-100 HbA1c calibrator pack and reagents demonstrated 90 days stability on the D-100 Hemoglobin Testing System.
Traceability	The assigned HbA1c value of the Glycosylated hemoglobin (HbA1c) test kit is certified with the National Glycohemoglobin Standardization Program (NGSP).	The D-100 HbA1c test standardization is traceable to the International Federation of Clinical Chemistry (IFCC) reference calibrators. The D-100 HbA1c assay is NGSP certified.

7. Non-clinical Performance Evaluation

The assigned HbA1c values of the Automatic Immunoassay Analyzer (Model: HP-AFS/1) is certified with the National Glycohemoglobin Standardization Program (NGSP). See NGSP website for current certification at http://www.ngsp.org.

The following performance data were provided in support of the substantial equivalence determination.

7.1 Precision

Precision experiments were performed for the Glycosylated hemoglobin Test Kit based on CLSI Guideline EP5-A3 using four EDTA K2 whole blood samples with targeted HbA1c concentrations (5.2%, 6.4%, 8.0% and 12.3%), two controls (6% and 11%).Samples were analyzed on three Automatic Immunoassay Analyzer instruments using three lots of reagents. Each sample was analyzed in duplicate per run, two runs per day for 20 days. The samples were randomized in experiment. The results are shown below:

Analyzer 1 precision:

Sample	Repeatability		Between run		Between day		Between lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
5.2%	0.107	2.0%	0.032	0.6%	0.000	0.0%	0.000	0.0%	0.111	2.1%
6.4%	0.179	2.8%	0.000	0.0%	0.000	0.0%	0.029	0.5%	0.182	2.8%
8.0%	0.162	2.0%	0.000	0.0%	0.000	0.0%	0.020	0.2%	0.163	2.0%
12.3%	0.145	1.2%	0.051	0.4%	0.000	0.0%	0.017	0.1%	0.155	1.2%

6%	0.176	2.9%	0.000	0.0%	0.000	0.0%	0.020	0.3%	0.177	2.9%
11%	0.189	1.7%	0.000	0.0%	0.000	0.0%	0.038	0.3%	0.193	1.8%

Analyzer 2 precision:

Sample	Repeatability		Between run		Between day		Between lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
5.2%	0.109	2.1%	0.000	0.0%	0.014	0.3%	0.000	0.0%	0.110	2.1%
6.4%	0.171	2.7%	0.000	0.0%	0.013	0.2%	0.000	0.0%	0.170	2.7%
8.0%	0.145	1.8%	0.000	0.0%	0.036	0.4%	0.000	0.0%	0.150	1.9%
12.3%	0.181	1.4%	0.026	0.2%	0.000	0.0%	0.000	0.0%	0.183	1.5%
6%	0.177	2.9%	0.000	0.0%	0.020	0.3%	0.027	0.5%	0.180	3.0%
11%	0.176	1.6%	0.000	0.0%	0.056	0.5%	0.000	0.0%	0.185	1.7%

Analyzer 3 precision:

Sample	Repeatability		Between run		Between day		Between lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
5.2%	0.093	1.8%	0.000	0.0%	0.011	0.2%	0.000	0.0%	0.094	1.8%
6.4%	0.163	2.6%	0.000	0.0%	0.033	0.5%	0.000	0.0%	0.166	2.6%
8.0%	0.243	3.0%	0.000	0.0%	0.000	0.0%	0.022	0.3%	0.244	3.0%
12.3%	0.145	1.2%	0.000	0.0%	0.063	0.5%	0.050	0.4%	0.166	1.3%
6%	0.192	3.2%	0.000	0.0%	0.000	0.0%	0.000	0.0%	0.192	3.2%
11%	0.147	1.3%	0.000	0.0%	0.039	0.4%	0.036	0.3%	0.156	1.4%

All analyzers precision:

Sample	Mean	Repeatability		Between run		Between day		Between lot		Between analyzer		Total	
	%	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
5.2%	5.23	0.103	2.0%	0.014	0.3%	0.000	0.0%	0.000	0.0%	0.010	0.2%	0.103	2.0%
6.4%	6.34	0.171	2.7%	0.000	0.0%	0.000	0.0%	0.011	0.2%	0.061	1.0%	0.171	2.7%

8.0%	8.03	0.188	2.3%	0.000	0.0%	0.000	0.0%	0.016	0.2%	0.031	0.4%	0.191	2.4%
12.3%	12.53	0.158	1.3%	0.011	0.1%	0.030	0.2%	0.028	0.2%	0.093	0.7%	0.188	1.5%
6%	6.04	0.182	3.0%	0.000	0.0%	0.000	0.0%	0.018	0.3%	0.006	0.1%	0.183	3.0%
11%	11.03	0.172	1.6%	0.000	0.0%	0.031	0.3%	0.030	0.3%	0.000	0.0%	0.177	1.6%

7.2 Method Comparison

A method comparison study was performed to compare the sample results from the candidate method, Hipro® Glycosylated hemoglobin (HbA1c) test kit on the Hipro HP-AFS/1 Automatic Immunoassay analyzer, to results from the Bio-Rad Hemoglobin Testing System. This study was conducted with the EDTA K2 whole blood samples.

One hundred and twenty (120) samples from the NGSP reference laboratory were used in the evaluation. These samples were measured by the NGSP reference laboratory using a Bio-Rad Hemoglobin Testing System (X axis) and by the Hipro® Glycosylated Hemoglobin (HbA1c) Test System (Y axis).

All acceptance criteria for method comparison were met. The difference plots show there is good agreement between the Hipro® Glycosylated Hemoglobin (HbA1c) Test System and the NGSP Bio-Rad Hemoglobin Testing System.

The table below summarizes the bias between the Hipro Glycosylated Hemoglobin (HbA1c) Test System and the NGSP's Bio-Rad Hemoglobin Testing System.

	Hipro Glycosylated Hemoglobin (HbA1c) Test System
Mean bias vs. NGSP Bio-Rad	-0.0148
Mean bias at lower 95% CI	-0.0470
Mean bias at upper 95% CI	0.0174

Bias at Concentration Data Summary

Concentration	Bias	% Bias
5.23%	-0.0262	-0.5%
6.34%	-0.0163	-0.26%
8.03%	-0.0012	-0.02%
12.53%	0.0388	0.31%

7.3 Total Error

Using the results of bias estimation (%Bias) in the method comparison study and precision estimates in the precision study, the Total Error (TE) at the following concentrations (5.2%, 6.4%, 8.0% and 12.3%) near the cut-off was calculated as follows:

%TE =|%Bias| + 1.96 * %CV * (1+%Bias/100)

The results are presented in the tables below.

Concentration	|%Bias|	CV%	%TE
5.23%	0.5%	2.0	4.4
6.34%	0.26%	2.7	5.5
8.03%	0.02%	2.4	4.7
12.53%	0.31%	1.5	3.3

7.4 Linearity

One dilution series consisting of 9 levels were prepared using the EDTA K2 WB sample pools with HbA1c through mixing high and low concentrations at the upper and lower end of the measuring range. Samples were measured in triplicate and data analysis was done separately for each sample. Linear regression analysis was done according to EP6-2nd edition. Study result is provided in the table below.

Analyte	Low End of Linear Range (%)	High End of Linear Range (%)	Slope	Intercept	R
HbA1c	4.3	14	1.0225	-0.1524	0.999

7.5 Endogenous Interference

A study evaluated several endogenous substances for potential interference with the measure of % HbA1c. The following five endogenous substances were evaluated:

Lipemia	Bilirubin	Glucose	Rheumatoid Factor	Total Protein

Pooled whole blood samples with two HbA1c levels, one near the medical decision level and one above it, were spiked with the maximum level of the above five interferents in separate preparations resulting in 10 spiked samples. Another pool, without interferent, was equally prepared. A 10-level dilution series was then created for each of the 10 spiked samples by using the interferent free pool as the diluting reagent.

The experiment was performed with one reagent lot, one Hipro HP-AFS/1 Automatic Immunoassay analyzer, and in a single run from the same calibration. The ten dilution series were

tested ten-fold for % HbA1c using the EDTA K2 WB sample only.

The mean of the ten replicates was determined and compared to the result from the reference sample (no interfering substance). The comparison was evaluated as a percent deviation. An interferent will be significant if it causes >7% deviation of a measurement in terms of % HbA1c.

Interferent	Highest Tested Concentration without Significant Interference
Lipemia	600mg/dL
Unconjugated Bilirubin	60mg/dL
Conjugated Bilirubin	60mg/dL
Glucose	9000mg/dL
Rheumatoid Factor	100IU/mL
Total Protein	15g/dL

7.8 Drug Interference

A study evaluated several drugs for potential interference with the measurement of %HbA1c using the EDTA K2 WB sample. The following drugs were studied:

Potential Interferent	Highest Tested Concentration without Significant Interference
N-Acetylcysteine	166mg/dL
Ampicillin-Na	100mg/dL
Ascorbic acid	30mg/dL
Cefoxitin	250mg/dL
Heparin	5000 U/L
Levodopa	2mg/dL
Methyldopa	2mg/dL
Metronidazole	20mg/dL
Doxycycline	5mg/dL
Acetylsalicylic acid	100mg/dL
Rifampicin	6mg/dL
Cyclosporin	1.66mg/dL
Phenylbutazone	40mg/dL
Acetaminophen	20mg/dL
Ibuprofen	50mg/dL
Theophylline	10mg/dL

The 16 commonly used drugs listed above were added to native patient samples and examined for potential effect on % HbA1c determination. Drug interference testing was performed with EDTA K2 WB samples at 2 different HbA1c levels. The two different HbA1c concentrations will be approximately 6.5% and 8.5% HbA1c. Each drug was added in two defined concentrations with concentration 1 being several times (typically 5 times) the maximum daily dosage and concentration 2 being the maximum daily dosage level. Samples were measured in ten-fold using the Hipro® Glycosylated Hemoglobin (HbA1c) Test System. The median value was compared to the reference value (HbA1c sample with no drug added) and the deviation from the reference was calculated.

Significant interference is defined as > ±7% deviation from the reference value observed. All acceptance criteria for drug interferences were met.

7.9 Cross-reactivity

Studies were performed to determine if the Hipro® Glycosylated hemoglobin (HbA1c) test kit demonstrates cross-reactivity with any of the following hemoglobin fractions and glycated albumin.

Hb A0	Carbamylated Hb	Glycated Albumin
Labile Hb A1c	Acetylated Hb	HbA1a+b

7.10 Hemoglobin variants

Hemoglobin variant testing was conducted to determine if there was any significant interference with any of the major hemoglobin variants and the Hipro® Glycosylated hemoglobin (HbA1c) test kit. Hemoglobin variants are structurally altered hemoglobin molecules with at least one amino acid exchange compared to the normal beta chain of hemoglobin. These changes are caused by mutations in the coding region of the globin genes which encode the protein part of hemoglobin. The most common hemoglobin variants are HbS, HbC, HbD and HbE. Moreover, in some conditions, the fetal hemoglobin HbF is elevated. Also, the erythrocytes of some patients (e.g. beta thalassemia minor) contain elevated levels of HbA2. Therefore, it is crucial to ensure accurate HbA1c results from patients who are carriers of these variants.

Hemoglobin Variant	Number of Samples	Variant Concentration Range (%)	Range of%HbA1c Concentration
HbC	20	25 - 66.6%	4.7-9.7
HbD	20	12.9 - 41.1%	5.2-10.2
HbE	20	13.8 - 30.5%	5.1-12.2
HbF	20	1.3 - 40.5%	4.4-8.4

HbS	20	16.8 – 76.9%	5.1-9.4
HbA2	20	3.1 – 6.4%	4.7-9.7

Each sample was tested twice on one Hipro HP-AFS/1 Automatic Immunoassay analyzer. Results obtained with the Hipro® Glycosylated hemoglobin (HbA1c) test kit on the Hipro HP-AFS/1 Automatic Immunoassay analyzer will be compared to those obtained with the reference methods. Results are summarized in the table below.

	Percent Relative Bias from Reference Method at Low and High Concentrations of HbA1c Samples			
	~6.5 % HbA1c		~9.0% HbA1c	
Hb Variant	Average	Range (%)	Average	Range (%)
HbC	-0.17	-3.77~3.77	2.27	-1.15~4.11
HbD	1.67	-1.79~5.08	2.10	1.16~3.03
HbE	1.58	-1.67~5.36	1.38	0.00~4.17
HbF	Interference was observed when the concentration of HbF is > 8%.			
HbS	1.69	-3.08~6.15	1.20	1.08~1.35
HbA2	1.57	-1.79~5.00	-0.51	-1.02~0.00

8. Clinical testing

Not applicable.

9. Other information (such as required by FDA guidance/Test)

Not applicable.

10. Conclusions Drawn from Non-Clinical and Clinical Tests

The Hipro® Glycosylated Hemoglobin (HbA1c) Test System is substantially equivalent to the legally marketed predicate device Bio-Rad D-100™ HbA1c (K151321).