January 6, 2026

Shanghai Medconn Medical Technology Co., Ltd.
% Jessie Mu, Project Manager
Guangdong Grzan Group Co., Ltd.
Rm 103-108, 1st Floor, Block B, Bldg 2, Bangkai Science and
Technology Park, Guanguang Road, Guangming District
Shenzhen, 518107
China

Re: K252749
Trade/Device Name: Medconn 8K Glycated Hemoglobin Test System
Regulation Number: 21 CFR 862.1373
Regulation Name: Hemoglobin A1c Test System
Regulatory Class: Class II
Product Code: PDJ, LCP
Dated: September 16, 2025
Received: September 16, 2025

Dear Jessie Mu:

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
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252749

Please provide the device trade name(s).

Medconn 8K Glycated Hemoglobin Test System

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

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

012_510k Summary (Summary of Safety and Effectiveness)

This 510(k) Summary is being submitted in accordance with requirements of Title 21 CFR 862.1373.

The assigned 510(k) Number: K252749
Date of Preparation:2026-01-05

1. Applicant information:

Submitter Name: Shanghai Medconn Medical Technology Co., Ltd.
Submitter Address: No.1018 Weichang Road, Shanyang Town Jinshan District 201508 Shanghai, China
Contact Person: Judan Guan (Regulatory Affairs Director)
Telephone Number: +0086 13817317440
Email: guanjudan@medconn.com

2. Correspondent's information:

Guangdong Grzan Group Co., Ltd.
Address: Room 103-108, 1st Floor, Block B,Building 2, Bangkai Science and Technology Park, Guanguang Road, Guangming District, Shenzhen, Guangdong, China
Contact Person: Jessie Mu
E-mail: jessie@grzan.cn

3. Device Name/Trade Name

Trade Name: Medconn 8K Glycated Hemoglobin Test System
Models: MQ-8000/MQ-8000PT
Classification Name: Hemoglobin A1c test system
Common Name: Hemoglobin A1c test system
Product Code: PDJ, LCP
Regulation Number: 21 CFR 862.1373
Regulation Class: 2
Review Panel: Clinical Chemistry
Regulation Medical Specialty: Clinical Chemistry
Type of 510(k) submission: Traditional

4. Predicate Device:

Trade Name:D-100™ HbA1c

D-100™ HbA1c Calibrator Pack

510(k) Submitter/holder: BIO-RAD LABORATORIES, INC.

510(k) Number: K151321

5. Description of the Device:

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

A high-pressure pumping system delivers a buffer solution to an analytical cartridge and detector. Whole blood samples undergo an automatic hemolysis and dilution process before being introduced into the analytical flow path. Manually hemolyzed and prediluted samples loaded in sample cups at 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.

Medconn 8K Glycated Hemoglobin Test System contains the following components:

- Medconn 8K Glycated Hemoglobin Analyzer
- Medconn 8K HbA1c Assay Kit (HPLC)
- Medconn Hemoglobin A1c Calibrator
- Medconn Hemoglobin A1c Control
- Medconn 8K HbA1c Column Kit (HPLC)
- Medconn HbA1c Haemolyser

6. Indications 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.

7. Substantial Equivalence Information:

Predicate Device Information:

Predicate Device Name	**Predicate Device 510(k) Number**
D-100™ HbA1c D-100™ HbA1c Calibrator Pack	K151321

The comparison of the technological characterizes of Medconn 8K Glycated Hemoglobin Test System (candidate assay) utilizes principles of ion-exchange high-performance liquid chromatography (HPLC) similar to the same technology of the predicate device.

Table below provides the similarities and differences between the candidate assay and the predicate assay.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Remark S/D**
510(K) Number	/	K151321	NA
Applicant	Shanghai Medconn Medical Technology Co.,Ltd.	BIO-RAD LABORATORIES, INC.	NA
Device Name	Medconn 8K Glycated Hemoglobin Test System	D-100™ HbA1c D-100™ HbA1c Calibrator Pack	NA
Instrument Platform	Medconn 8K Glycated Hemoglobin Analyzer	D-100™ Hemoglobin Testing System	NA
Regulation number	21 CFR 862.1373	21 CFR 862.1373	SE
Regulatory Class	2	2	SE

Product Code	PDJ, LCP	PDJ, LCP, JIT	SE
Intended 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.	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, 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 Bio-Rad D-100™ HbA1c test is intended for Professional Use Only.	SE
Type of Use	Prescription Use	Prescription Use	SE
System Composition	Medconn 8K Glycated Hemoglobin Analyzer Medconn 8K HbA1c Assay Kit (HPLC) Medconn 8K HbA1c Column Kit (HPLC) Medconn HbA1c Haemolyser Medconn Hemoglobin A1c Calibrator Medconn Hemoglobin A1c Control	D-100™ Hemoglobin Testing System Bio-Rad D-100 HbA1c assay D-100 TM HbA1c Analytical Cartridge/Calibrator Pack Lyphochek® Diabetes Control（k070546） Bio-Rad Laboratories LiquichekTM Diabetes Control（k052838）	SE
Test principle	Ion exchange HPLC	Ion exchange HPLC	SE
Sample Types	Human Whole Blood	Human Whole Blood	SE
Matrices	K2-EDTA	K2-EDTA, K3-EDTA Potassium Oxalate/Sodium Fluoride, Sodium Citrate, Sodium Heparin, Lithium Heparin	SE

Measuring interval	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)	Difference
Standardization	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).	SE

Both the subject device (Medconn 8K Glycated Hemoglobin Test System) and the Predicate device (D-100™ HbA1c, D-100™ HbA1c Calibrator Pack) have the same intended use, principle of operation, intended user, use environment and the similar technological characteristics.

Only the measuring interval is little different (subject device: 3.0% to 17.0%(NGSP) and 9.3~162.3mmol/mol HbA1c (IFCC); predicate device: 3.5% to 20% (NGSP) and 15~195 mmol/mol HbA1c (IFCC), and the analytical performance validation demonstrates that the subject device can cover the claimed measuring interval, and it does not raise any new questions of safety or effectiveness. Thus, the subject device is substantially equivalent to the predicate device.

8. Summary of Performance Data:

(1) Analytical performance

a. Precision/Reproducibility:

Precision of the Medconn 8K Glycated Hemoglobin Test System was evaluated based on CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition. Four K2-EDTA whole blood samples at concentrations near 5% (31.1mmol/mol), 6.5%(47.5mmol/mol), 8%(63.9mmol/mol) , 12% (109.8mmol/mol) HbA1c and two-level quality control products were analyzed in duplicate, twice a day, with three lots of reagents, over 20 non-consecutive days, on three MQ-8000 Glycated Hemoglobin Analyzers with two opreation modes(whole blood mode and dilution mode). For each sample there were 720 measurements. Results are shown in the tables below:

Variation Source	Instrument 1 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4

	5.50	11.07	5.13	6.70	8.01	12.16
Repeatability	1.16%	0.72%	0.87%	0.86%	0.65%	0.63%
Between-Run	0.0*	0.0*	0.13%	0.22%	0.35%	0.26%
Between-Day	0.31%	0.23%	0.27%	0.0*	0.0*	0.0*
Between-Lot	0.0*	0.05%	0.0*	0.11%	0.11%	0.06%
Total Precision	1.17%	0.73%	0.92%	0.88%	0.73%	0.67%
Variation Source	Instrument 2 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	5.49	11.06	5.13	6.70	8.01	12.17
Repeatability	1.18%	0.69%	0.87%	0.83%	0.78%	0.63%
Between-Run	0.39%	0.17%	0.22%	0.17%	0.29%	0.05%
Between-Day	0.0*	0.0*	0.06%	0.11%	0.08%	0.24%
Between-Lot	0.22%	0.03%	0.07%	0.02%	0.0*	0.04%
Total Precision	1.25%	0.71%	0.90%	0.86%	0.83%	0.67%
Variation Source	Instrument 3 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	5.50	11.06	5.13	6.71	8.00	12.16
Repeatability	1.18%	0.70%	0.94%	0.80%	0.69%	0.59%
Between-Run	0.26%	0.10%	0.18%	0.33%	0.0*	0.11%
Between-Day	0.0*	0.07%	0.0*	0.05%	0.25%	0.23%
Between-Lot	0.10%	0.0*	0.08%	0.09%	0.0*	0.10%
Total Precision	1.16%	0.71%	0.93%	0.87%	0.72%	0.65%

Variation Source	Combined % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	5.50	11.06	5.13	6.70	8.01	12.16
Repeatability	1.17%	0.70%	0.90%	0.83%	0.71%	0.62%
Between-Run	0.23%	0.03%	0.18%	0.25%	0.26%	0.17%
Between-Day	0.0*	0.14%	0.06%	0.00%	0.11%	0.17%
Between-Lot	0.12%	0.02%	0.06%	0.09%	0.0*	0.07%
Between-Instrument	0.09%	0.01%	0.0*	0.0*	0.0*	0.0*
Total Precision	1.20%	0.72%	0.91%	0.87%	0.76%	0.66%

Table 1: Results of Precision Study of whole blood mode (NGSP%)

Variation Source	Instrument 1 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	36.62	97.43	32.55	49.70	63.95	109.35
Repeatability	1.38%	0.79%	1.15%	0.96%	0.66%	0.72%
Between-Run	0.40%	0.0*	0.0*	0.11%	0.43%	0.12%
Between-Day	0.33%	0.26%	0.35%	0.17%	0.0*	0.04%
Between-Lot	0.0*	0.06%	0.0*	0.0*	0.12%	0.05%
Total Precision	1.47%	0.82%	1.18%	0.97%	0.77%	0.73%
Variation Source	Instrument 2 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	36.49	97.36	32.48	49.69	63.97	109.41
Repeatability	1.50%	0.82%	1.18%	0.91%	0.80%	0.69%

Between-Run	0.39%	0.18%	0.49%	0.23%	0.22%	0.11%
Between-Day	0.0*	0.12%	0.0*	0.24%	0.12%	0.26%
Between-Lot	0.16%	0.0*	0.06%	0.08%	0.07%	0.02%
Total Precision	1.52%	0.85%	1.24%	0.97%	0.85%	0.75%
Variation Source	Instrument 3 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	36.56	97.31	32.54	49.75	63.96	109.28
Repeatability	1.44%	0.82%	1.20%	0.88%	0.69%	0.67%
Between-Run	0.47%	0.14%	0.42%	0.36%	0.21%	0.09%
Between-Day	0.0*	0.04%	0.0*	0.19%	0.27%	0.23%
Between-Lot	0.11%	0.09%	0.04%	0.05%	0.0*	0.12%
Total Precision	1.46%	0.83%	1.20%	0.97%	0.77%	0.72%
Variation Source	Combined % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	36.56	97.37	32.52	49.72	63.96	109.34
Repeatability	1.44%	0.81%	1.17%	0.92%	0.72%	0.69%
Between-Run	0.42%	0.10%	0.35%	0.25%	0.31%	0.11%
Between-Day	0.0*	0.17%	0.0*	0.20%	0.11%	0.20%
Between-Lot	0.07%	0.06%	0.0*	0.0*	0.06%	0.08%
Between-Instrument	0.13%	0.0*	0.09%	0.0*	0.0*	0.0*
Total Precision	1.49%	0.83%	1.21%	0.97%	0.79%	0.73%

Table 2: Results of Precision Study of whole blood mode (IFCC mmol/mol)

Variation Source	Instrument 1 % CV by Sample					
	5.49	11.06	5.14	6.41	7.91	12.04
	1.08%	0.61%	0.95%	0.82%	0.77%	0.74%
Repeatability	0.35%	0.30%	0.0*	0.36%	0.24%	0.11%
Between-Run	0.22%	0.0*	0.21%	0.0*	0.0*	0.19%
Between-Day	0.24%	0.0*	0.0*	0.09%	0.10%	0.05%
Between-Lot	1.18%	0.67%	0.96%	0.87%	0.81%	0.78%
Total Precision	5.49	11.06	5.14	6.41	7.91	12.04
Variation Source	Instrument 2 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	5.50	11.07	5.15	6.41	7.92	12.05
Repeatability	1.12%	0.69%	0.94%	0.87%	0.75%	0.71%
Between-Run	0.20%	0.25%	0.38%	0.0*	0.0*	0.23%
Between-Day	0.0*	0.15%	0.0*	0.13%	0.11%	0.0*
Between-Lot	0.0*	0.0*	0.0*	0.21%	0.0*	0.06%
Total Precision	1.12%	0.75%	0.97%	0.84%	0.75%	0.72%
Variation Source	Instrument 3 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	5.50	11.06	5.15	6.41	7.91	12.06
Repeatability	1.10%	0.69%	0.96%	0.96%	0.73%	0.65%
Between-Run	0.20%	0.12%	0.0*	0.0*	0.26%	0.13%
Between-Day	0.33%	0.16%	0.35%	0.0*	0.10%	0.15%

Between-Lot	0.32%	0.0*	0.0*	0.14%	0.0*	0.09%
Total Precision	1.21%	0.71%	0.97%	0.89%	0.78%	0.68%
Variation Source	Combined % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	5.50	11.07	5.15	6.41	7.91	12.05
Repeatability	1.10%	0.67%	0.95%	0.89%	0.75%	0.70%
Between-Run	0.26%	0.24%	0.07%	0.0*	0.19%	0.16%
Between-Day	0.20%	0.10%	0.18%	0.0*	0.06%	0.05%
Between-Lot	0.23%	0.0*	0.0*	0.15%	0.02%	0.07%
Between-Instrument	0.0*	0.05%	0.05%	0.0*	0.0*	0.0*
Total Precision	1.17%	0.71%	0.97%	0.86%	0.78%	0.73%

Table 3: Results of Precision Study of dilution mode (NGSP%)

Variation Source	Instrument 1 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	36.57	97.38	32.64	46.54	62.93	108.10
Repeatability	1.32%	0.75%	1.17%	0.93%	0.80%	0.76%
Between-Run	0.55%	0.24%	0.0*	0.50%	0.20%	0.14%
Between-Day	0.43%	0.0*	0.41%	0.0*	0.11%	0.18%
Between-Lot	0.16%	0.04%	0.0*	0.09%	0.05%	0.04%
Total Precision	1.51%	0.78%	1.22%	1.04%	0.83%	0.79%
Variation Source	Instrument 2 % CV by Sample					

	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	36.60	97.48	32.69	46.45	62.90	108.14
Repeatability	1.43%	0.76%	1.21%	1.06%	0.79%	0.72%
Between-Run	0.30%	0.20%	0.33%	0.0*	0.0*	0.27%
Between-Day	0.07%	0.26%	0.0*	0.11%	0.13%	0.0*
Between-Lot	0.0*	0.09%	0.13%	0.14%	0.0*	0.02%
Total Precision	1.47%	0.84%	1.21%	1.02%	0.79%	0.73%
Variation Source	Instrument 3 % CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	36.55	97.33	32.68	46.51	62.89	108.25
Repeatability	1.40%	0.80%	1.28%	1.06%	0.75%	0.71%
Between-Run	0.29%	0.01%	0.0*	0.0*	0.21%	0.02%
Between-Day	0.33%	0.18%	0.28%	0.0*	0.14%	0.19%
Between-Lot	0.48%	0.0*	0.0*	0.17%	0.01%	0.14%
Total Precision	1.54%	0.81%	1.24%	1.02%	0.79%	0.75%
Variation Source	Combined% CV by Sample					
	Control 1	Control 2	Sample 1	Sample 2	Sample 3	Sample 4
	36.58	97.40	32.67	46.50	62.91	108.17
Repeatability	1.39%	0.77%	1.22%	1.02%	0.78%	0.73%
Between-Run	0.40%	0.18%	0.0*	0.16%	0.17%	0.17%
Between-Day	0.32%	0.18%	0.20%	0.0*	0.13%	0.08%
Between-Lot	0.29%	0.03%	0.01%	0.14%	0.0*	0.09%

Between-Instrument	0.0*	0.05%	0.05%	0.0*	0.0*	0.01%
Total Precision	1.49%	0.81%	1.23%	1.03%	0.80%	0.76%

Table 4: Results of Precision Study of dilution mode (IFCC mmol/mol)

b.Linearity

A linearity study was performed based on CLSI EP06-A2: Evaluation of the Linearity of Quantitative Measuring Procedures, 2nd Edition; Linearity across the reportable range/measuring range was performed using altered patient samples collected using K2-EDTA.

Dilution mode: Samples were prepared by diluting the high concentration samples and the low concentration samples with the Medconn HbA1C Haemolyser to obtain a low HbA1c of 3.1% (10.4 mmol/mol) and a high HbA1c of 17.1% (163.4 mmol/mol). These high and low samples were mixed together in varying ratios to obtain 9 additional intermediate sample levels. The eleven test samples (high, low and 9 intermediates) were run three times with 3 lots of reagents on one instrument; measured values were compared to theoretical values.

Whole blood mode: A low HbA1c of 3.1% (10.4 mmol/mol) and a high HbA1c of 17.1% (163.4 mmol/mol) were mixed together in varying ratios to obtain 9 additional intermediate sample levels. The eleven test samples (high, low and 9 intermediates) were run three times with 3 lots of reagents on one instrument with two operation modes(dilution mode and whole blood mode); measured values were compared to theoretical values.

The maximum Bias(mean) between observed value and theoretical value were ±0.2 (NGSP %) and ±2(IFCC mmol/mol).

The regression parameters (slope, intercept, and R^2) were the following:

Reagent lot	**Units/Values**	**Slope**	**Intercept**	**R^2**
Lot 1	NGSP	0.9913	0.0056	0.9999
Lot 2	NGSP	0.9946	-0.0393	0.9999
Lot 3	NGSP	0.9922	-0.0031	0.9999
Lot (mean)	NGSP	0.9927	-0.0123	0.9999

Table 5: Results of regression parameters of whole blood mode (NGSP %)

Reagent lot	Units/Values	Slope	Intercept	R^2
Lot 1	IFCC	0.9913	-0.1420	0.9999
Lot 2	IFCC	0.9946	-0.5566	0.9999
Lot 3	IFCC	0.9922	-0.2172	0.9999
Lot (mean)	IFCC	0.9927	-0.3053	0.9999

Table 6: Results of regression parameters of whole blood mode (IFCC mmol/mol)

Lot 1	NGSP	0.9935	-0.0374	0.9999
Lot 2	NGSP	0.9916	-0.0208	0.9999
Lot 3	NGSP	0.9924	-0.0295	0.9999
Lot (mean)	NGSP	0.9925	-0.0292	0.9999

Table 7: Results of regression parameters of dilution mode (NGSP %)

Reagent lot	Units/Values	Slope	Intercept	R^2
Lot 1	IFCC	0.9935	-0.5619	0.9999
Lot 2	IFCC	0.9916	-0.4257	0.9999
Lot 3	IFCC	0.9924	-0.501	0.9999
Lot (mean)	IFCC	0.9925	-0.4962	0.9999

Table 8: Results of regression parameters of dilution mode (IFCC mmol/mol)

The linearity study was reviewed and found acceptable. Results of the linearity study support the claimed measuring range of the device of 3.0% to 17.0% HbA1c (9.3-162.3mmol/mol).

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

Traceability:

Medconn 8K Glycated Hemoglobin Test System standardization is traceable to the International Federation of Clinical Chemistry (IFCC) reference calibrators.

HbA1c results are provided to users in two different units: NGSP equivalent units (%) and IFCC equivalent units (mmol/mol). Results in % HbA1c from the NGSP correlation are calculated from the individual quantitative results for Hemoglobin A1c. The IFCC units of mmol/mol are calculated using the Master Equation: NGSP (%) = 0.09148 x IFCC (mmol/mol) + 2.152.

d. Detection limit:

Not applicable.

e. Analytical specificity:

i. Endogenous Interference

An Endogenous Interference study was performed per CLSI EP07-A3, Interference Testing in Clinical Chemistry. Two EDTA whole blood sample pools were evaluated using a low level whole blood sample with a concentration ~6.5% HbA1c and a high level whole blood sample with a concentration of HbA1c of ~8.0%.

Unconjugated Bilirubin, Conjugated Bilirubin, glucose and lipemia(Triglycerides), available in pure form, were obtained and stock solutions prepared at 10x the intended test concentration. The 10x stock solution of the test substance was pipetted into a low whole blood sample pool (at ~6.5% HbA1c) and a high whole blood sample pool (~8.0% HbA1c), making the test pool. Ten replicates of each pool prepared with the test and control samples were analyzed using the MQ-8000 Testing System.

Rheumatoid factor, lipemia and total protein were not available as pure standards therefore serum samples with known concentration of these compounds were used. The test pool was prepared by mixing the serum sample known to have a high test substance concentration with a whole blood non-variant sample such that the concentration of test substance in the final mixture would be at the desired level. Ten replicates of each pool prepared with the test and control samples were analyzed using the MQ-8000 Testing System.

Significant interference was defined as a ± 6% change in %HbA1c value from the control. Results in Table 9 showed no significant interference up to the stated concentrations.

Table 9: Endogenous Interference Study Results

Interfering substance	Concentration with No Interference

Unconjugated bilirubin	21.3 mg/dL
Conjugated bilirubin	19.2 mg/dL
Lipemia (Triglycerides)	6000 mg/dL
RF(rheumatoid factors)	750 IU/mL
TP(total protein)	21.0 g/dL

ii. Drug Interference

A Drug Interference study was performed based per CLSI EP07-A3, Interference Testing in Clinical Chemistry. Two EDTA whole blood sample pools were evaluated using a low level whole blood sample with a concentration ~6.5%HbA1c and a high level whole blood sample with a concentration of ~8.0%HbA1c. Ten replicates of each drug prepared with the test and control samples were analyzed using the MQ-8000 Testing System.

With Hplc, the red cells are lysed and eluted across the column for separation of the hemoglobin fractions. Research of the FDA website and others show no Contraindication of Levodopa, Methyldopa, Acetaminophen and ibuprofen when used by pre-diabetic or diabetic patients, and the drugs do not interfere with the Hplc technology as they might during an antigen antibody reaction, FDA stated that based On the technology of the device, it has been shown that the additional substances do not appear to interfere with this type of device, therefore, the additional interference data on these drugs was not needed.

Significant interference was defined as a more than ± 6% change in %HbA1c value from the control. No significant interference was observed at therapeutic levels up to the stated concentrations in Table 10 on the following page.

Table 10: Drug Interference Study Results

Interfering substance	Concentration with No Interference
Ascorbic acid	100 mg/dL
Acetylcysteine	166 mg/dL
Ampicillin-Na	1,000 mg/dL
Cefoxitin	2,500 mg/dL
Heparin	5,000 U/L
Levodopa	20 mg/dL
Methyldopa	20 mg/dL
Metronidazole	200 mg/dL
Doxycyclin	50 mg/dL
Rifampicin	64 mg/dL
Cyclosporine	5 mg/dL

Acetaminophen	200 mg/dL
Ibuprofen	500 mg/dL
Theophylline	100 mg/dL
Phenylbutazone	400 mg/dL

iii. Cross Reactivity with Hemoglobin Derivatives

A Hemoglobin Derivatives Interference study was performed based on CLSI EP07-A3, Interference Testing in Clinical Chemistry. Potential interference from Acetylated hemogloblin (Hb), Carbamylated hemoglobin (Hb) and Labile HbA1c were evaluated using a low level whole blood EDTA sample with a concentration ~6.5%HbA1c and a high level whole blood EDTA sample with a concentration of ~8.0% HbA1c. The potentially interfering hemoglobin derivatives were spiked into the low and high level blood samples and each sample was analyzed using ten replicates each in the same analytical run on the MQ-8000 Testing System.

Significant interference was defined as more than a ±6% change in HbA1c value from the control. The test result conclusions are as follows:

• Acetylated Hb (Acetylsalicylic acid up to 500 mg/dL) does not interfere with this assay.

• Carbamylated Hb (Potassium cyanate up to 10 mg/dL) does not interfere with this assay.

• Labile A1c- (Glucose up to 2000 mg/dL, Acetaldehyde up to 60 mg/dL) does not interfere with this assay.

Results showed there was no cross reactivity with these substances at physiological levels.

iv. Hemoglobin Variant Interference

Two hemoglobin variant studies were performed using a panel of normal and diabetic whole blood EDTA patent variant samples known to contain hemoglobin variants S, C, E, D, A2 and F. Testing of the samples containing hemoglobin variants S, C, E, D , A2 and F were performed in duplicate using the MQ-8000 Testing System and compared to results obtained by reference methods that have been demonstrated to be free from interference with the hemoglobin variant being tested. Table 11-1&11-2 contains the number of samples, range of samples and concentration of samples used in the Hemoglobin Variant Study. Table 12-1& 12-2 contains the results for the hemoglobin variant study bias.

Hemoglobin Variant	n	Range in % Abnormal Variant	Range in %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

Table 11-1: Variant samples used in hemoglobin variants study

Hemoglobin Variant	n	Range in % AbnormalVariant	Rangein % HbA1c Concentration
HbE	10	25.4 – 31.2	5.1 – 10.2
HbF	11	25.6– 34.5	5.1 – 11.2

Table 11-2: Variant samples used in hemoglobin variants study(supplementary data)

HemoglobinVariant	Relative % Bias to Comparative Method	
	Relative %Bias (Range of %Bias) forHbA1c	Relative %Bias (Range of %Bias)for HbA1c
	~ 6.5%	~ 8.0%
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)

Table 12-1: Results of hemoglobin variants study

HemoglobinVariant	Relative % Bias to Comparative Method	
	Relative %Bias (Range of %Bias) for HbA1c	Relative %Bias (Range of %Bias) for HbA1c
	~ 6.5%	~ 8.0%
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)

Table 12-2: Results of hemoglobin variants study (supplementary data)

No significant interference was observed for HbC (≤38%), HbD (≤43%), HbS (≤42%), HbE (≤ 31.2%), HbA2 (≤ 5.6%) and HbF (≤34.5%) at the concentrations tested in this study.

f. Assay cut-off:

Not applicable.

(2) Comparison studies

a. Method comparison with a standardized test method:

A Method comparison study was performed per CLSI EP09c 3rd Edition, Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 139 variant-free whole blood K2-EDTA samples, ranging from 3.0% to 17.0% HbA1c were evaluated using MQ-8000PT analyzer on the Medconn 8K Glycated Hemoglobin Test System. 139 samples were tested, and the results were compared to testing performed at by a NGSP Secondary Reference Laboratory using a previously cleared HPLC HbAlc assay method (BIO-RAD D-100 analyzer). To support the diagnostic claim, the distribution of samples spanned around the clinical decision point as follows in the table below.

Sample distribution in the method comparison study

Hemoglobin A1c level	Number of samples	% of Samples
≤ 5%	9	6.5
5 – 6%	15	10.8
6 – 6.5%	34	24.5
6.5 – 7%	35	25.2
7 – 8%	18	12.9
8 – 9%	11	7.9
> 9%	17	12.2

Total samples	139	100.0

Bias between the Candidate and NGSP method

Deming (weighted) and Passing-Bablok regression analyses were performed for the MQ-8000PT analyzer versus the NGSP SRL reference method.

Summary of Method Comparison Results:

1) Dilution mode data:

	y-Intercept	95% CI	Slope	95% CI
Deming	0.1589	0.0173 to 0.3004	0.9855	0.9645 to 1.0066
PassingBablok	0.1000	0.1000 to 0.1000	1.0000	1.0000 to 1.0000

The following biases between the MQ-8000PT run on Medconn 8K Glycated Hemoglobin Test System versus the NGSP Reference Method (BIO-RAD D-100 analyzer) were observed:

%Decision Level (x)	Bias (Deming)	**%Bias** (Deming)
5.0	0.0864	1.7280
6.5	0.0647	0.9946
8.0	0.0429	0.5362
12.0	-0.0151	-0.1258

%Decision Level (x)	Bias (PassingBablok)	**%Bias** (PassingBablok)
5.0	0.1000	2.0000
6.5	0.1000	1.5385
8.0	0.1000	1.2500
12.0	0.1000	0.8333

Total Error Near the Cutoff:

Using the results of bias estimation (%Bias) in the method comparison study and precision estimates in the precision study, Total Error (TE) at four HbA1c concentrations (5.0%, 6.5% , 8.0% and 12.0%) was calculated as follows: %TE =|%Bias| + 1.96*%CV*(1+%Bias/100).

The results are presented in the tables below.

Total Error(**%TE)**-Deming：

HbA1c Level	**%TE**	%Bias	$\%CV_{Total}$
5.0%	3.66	1.73	0.97
6.5%	2.69	0.99	0.86
8.0%	2.08	0.54	0.78
12.0%	1.30	-0.13	0.73

Total Error(**%TE)**-PassingBablok：

HbA1c Level	**%TE**	%Bias	$\%CV_{Total}$
5.0%	3.94	2.00	0.97
6.5%	3.25	1.54	0.86
8.0%	2.80	1.25	0.78
12.0%	2.27	0.83	0.73

2) Whole blood mode data:

	y-Intercept	95% CI	Slope	95% CI
Deming	0.1619	-0.0062 to 0.3300	0.9868	0.9617 to 1.0120
PassingBablok	0.1000	0.0106 to 0.100	1.0000	1.0000 to 1.0118

The following biases between the MQ-8000PT run on Medconn 8K Glycated Hemoglobin Test System versus the NGSP Reference Method (BIO-RAD D-100 analyzer) were observed:

%Decision Level (x)	Bias (Deming)	**%Bias** (Deming)
5.0	0.0959	1.9180
6.5	0.0761	1.1708
8.0	0.0563	0.7038
12.0	0.0035	0.0292

%Decision Level (x)	Bias (PassingBablok)	**%Bias** (PassingBablok)
5.0	0.1000	2.0000
6.5	0.1000	1.5385
8.0	0.1000	1.2500
12.0	0.1000	0.8333

Total Error Near the Cutoff:

Using the results of bias estimation (%Bias) in the method comparison study and precision estimates in the precision study, Total Error (TE) at four HbA1c concentrations (5.0%, 6.5% , 8.0% and 12.0%) was calculated as follows: $\%TE = |\%Bias| + 1.96 * \%CV_{Total} * (1 + \%Bias/100)$.

The results are presented in the tables below.

Total Error(**%TE)**-Deming：

HbA1c Level	**%TE**	%Bias	$\%CV_{Total}$
5.0%	3.74	1.92	0.91
6.5%	2.90	1.17	0.87

8.0%	2.20	0.70	0.76
12.0%	1.32	0.03	0.66

Total Error(**%TE)**-PassingBablok：

HbA1c Level	**%TE**	%Bias	$\%CV_{Total}$
5.0%	3.82	2.00	0.91
6.5%	3.27	1.54	0.87
8.0%	2.76	1.25	0.76
12.0%	2.13	0.83	0.66

(3) Expected values/Reference range:

The sponsor provided the following expected values in the labeling:

As the recommendation from the American Diabetes Association:

Non-diabetic level <5.7%

Criteria for diagnosis of prediabetes level 5.7% - 6.4%

Criteria for diagnosis of diabetes level ≥ 6.5% (threshold)

The expected HbA1c range for non-diabetic adults is 4-6%

It is recommended that each laboratory establish its own reference values based on the characteristics of population.

9. Proposed Labeling

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

10. Conclusion

The information and data in this 510(k) document demonstrate that the Medconn 8K Glycated Hemoglobin Test System is an accurate, reliable, precise test that correlates well with current cleared methods and NGSP standardized testing for the quantitation of HbA1c. And the performance criteria as stipulated by the Special Controls requirements for HbA1c systems that diagnose diabetes have clearly been met.

The contents of this submission demonstrates that the Medconn 8K Glycated Hemoglobin Test System(Models: MQ-8000/MQ-8000PT), is substantially equivalent

to its predicate device, D-100™ HbA1c, therefore, safe and effective for its intended use.